

EXHIBIT 25

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**IN RE: JOHNSON & JOHNSON
TALCUM POWDER PRODUCTS
MARKETING, SALES PRACTICES,
AND PRODUCTS LIABILITY
LITIGATION**

MDL No. 16-2738 (MAS) (RLS)

***THIS DOCUMENT RELATES TO ALL
CASES***

**THIRD AMENDED EXPERT REPORT OF
LAURA M. PLUNKETT, PH.D., DABT**

Date: 28 May 2024

A handwritten signature in black ink, appearing to read "Laura M. Plunkett", is written over a horizontal line.

Laura M. Plunkett, Ph.D., DABT

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I. Training and Qualifications

1. I am a pharmacologist, toxicologist, United States Food and Drug Administration (FDA) regulatory specialist and partner in a consulting company known as BioPolicy Solutions, LLC. BioPolicy Solutions has offices in Houston, TX and Ventura, CA, and is a consulting firm that works at the interface of biological science, regulatory affairs, and business decisions to provide its clients with science-based solutions to issues associated with development and marketing of existing products as well as new technologies. Before BioPolicy Solutions was formed in June of 2020, I was principal in the consulting firm known as Integrative Biostrategies (2001 to May 2020) and head of a consulting firm known as Plunkett & Associates (1997 to 2001). Attached to this report as Appendix A is a copy of my curriculum vitae.

2. I am board-certified as a Diplomate of the American Board of Toxicology. I am a member of several professional organizations and have authored or co-authored numerous scientific publications. I have over twenty years of experience in the areas of pharmacology and toxicology and have worked in both government and academic research. I have taught pharmacology and toxicology at the undergraduate and postgraduate levels.

3. I received a B.S. degree in 1980 from the University of Georgia and a Ph.D. in pharmacology from the University of Georgia, College of Pharmacy in 1984. My doctoral research was focused on the area of cardiovascular pharmacology, and specifically dealt with delineating neurochemical mechanisms responsible for the cardiac toxicity of digitalis glycosides. My training required my understanding of the mechanisms of action and basic pharmacology of drugs from all classes.

4. From June 1984 through August 1986, I was a Pharmacology Research Associate Training (PRAT) fellow at the National Institute of General Medical Sciences, Bethesda, Maryland. I worked in a neuroscience laboratory of the National Institute of Mental Health. My research focused on the role of various brain neurochemical systems involved in the control of autonomic nervous system and cardiovascular function.

5. From September 1986 to June 1989, I was an Assistant Professor of Pharmacology and Toxicology in the medical school at the University of Arkansas for Medical Sciences, Little Rock, Arkansas, where I performed basic research in the areas of neuropharmacology and toxicology as well as cardiovascular pharmacology and toxicology. I taught courses for both medical students and graduate students in pharmacology and toxicology as well as the neurosciences. As a pharmacologist, my work was directed towards understanding the biologic mechanisms of drug actions.

6. From December 1989 to August 1997, I worked for ENVIRON Corporation, first in the Arlington, Virginia office and then in the Houston, Texas office. I worked specifically within the health sciences group and most of my projects dealt with issues surrounding products or processes regulated by the FDA. During my consulting career (ENVIRON, Plunkett & Associates, and Integrative Biostrategies), I have worked on a variety of projects dealing with the regulation of products by the FDA, including human drugs (both prescription and over-the-counter drugs), veterinary drugs, biologics, medical devices, cosmetics, consumer products, dietary supplements and foods. I have advised my clients on regulatory issues and strategies for their products, designed preclinical and clinical studies for both efficacy and safety, advised clients on issues related to statements regarding efficacy and warnings for their products based on the current labeling regulations, and generally acted as a regulatory affairs staff for small companies in early stages of product development. Among the clients that I have consulted with have been cosmetic ingredient manufacturers and manufacturers of finished cosmetic products, both large and small companies. A tool and generally accepted methodology common to all my work as a consultant would be risk assessment, including many projects where risks related to exposure to chemicals in consumer products were at issue. Also, as part of my risk assessment work, I commonly review and rely on epidemiology data, as well as animal and *in vitro* data in order to assess risks to human health.

7. With respect to my experience that is directly relevant to the issues in this case, I have done a great deal of work on projects related to regulation of cosmetics and cosmetic ingredients. As part of my regulatory practice as a consultant over more than 25 years, I have consulted with cosmetic ingredient manufacturers and manufacturers of cosmetic products on issues related to ingredient safety, product safety, labeling claims, and general regulatory

compliance issues which include US regulations and regulations in other countries. These projects have been for companies of different sophistication in terms of their knowledge of cosmetic regulatory compliance. In some cases, I have worked with large companies and provided advice on the safety of ingredients used to manufacture cosmetic products. In other cases, I have given advice to the company as part of an initial commercialization process, where the client was trying to decide how to market their product, *e.g.*, as a cosmetic or a drug, as well as to determine if their product was safe for human exposure. Prior to this litigation, I have worked on the safety of talc itself. In the 1990's, I consulted with companies making condoms, which are classified as medical devices,¹ and provided scientific advice on the safety of talcum powder that was used on the surfaces of the devices as a dry lubricant. This work included my assessment of the scientific literature, including epidemiology, animal and *in vitro* studies that discussed potential adverse health effects linked to talc exposure, including both local tissue toxicity and systemic toxicity.

8. Related to the issue of cosmetic ingredient safety is the issue of determining if that ingredient is “*generally-recognized-as-safe*”, or “GRAS”. In many of my projects, the issue of whether a consumer product ingredient is GRAS is critical to determining what type of toxicity testing is needed to establish that a product or an ingredient is safe for human use. Like the reviews performed on cosmetic ingredients by members of panels such as the Cosmetic Ingredient Review (CIR) panel (the role of the CIR process and its panel is discussed in more detail below), GRAS reviews that I have performed involved consideration of animal and human toxicity data, cellular and mechanistic data, human product experience reports, and the type and level of exposure that may occur when humans are exposed to the ingredient or product.

9. As a pharmacologist and board-certified toxicologist, much of my consulting work has related to understanding and explaining the mechanisms of action of chemicals of all types, as well as the toxic effects of these chemicals. I have expertise in pharmacokinetics, where I have designed clinical trials and analyzed pharmacokinetic data. I have taught pharmacology to medical students and graduate students. I have lectured to graduate students, law students and pharmacy students on FDA regulations as they apply to all types of FDA-regulated products, including cosmetics. Throughout my career, I have published dozens of peer-reviewed articles, which are

¹ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=HIS>

listed in my curriculum vitae (Appendix A). I have authored a book chapter on FDA pharmacovigilance practices. I have served as a peer-reviewer for medical journals in my capacity as a pharmacologist and toxicologist. In litigation, I have provided expert testimony and been qualified by both state and federal courts in the areas of pharmacology, pharmacokinetics, toxicology, risk assessment and FDA regulations. A list of my previous testimony for the past five years is included as Appendix B.

II. Information Reviewed and Methodology Employed

10. In the current case, I have been asked to provide opinions related to the human health hazards posed by exposure to talcum powder products and how those hazards relate to the regulatory requirements for marketing cosmetic ingredients and cosmetic products in the United States. I amended my original MDL report on 30 June 2021. I prepared a second amendment to my original MDL report on 15 November 2023. This is a third amendment to my original MDL report and has been prepared to address new published peer-reviewed articles that relate to opinions I have expressed in this litigation. I am prepared to provide testimony on many of the topics addressed in my earlier reports (dated October 5, 2016, August 29, 2018, November 16, 2018, June 30, 2021, and November 15, 2023), as well as opinions contained in testimony during hearings, depositions, and trials. This report contains discussion of additional documents, scientific literature, reports, and deposition testimony that has become available since preparing my original report in October 2016 and my reports dated in 2018, 2021, and 2023. To provide a general summary, the relevant materials I have reviewed during the course of continuing work in this litigation include the following:

- a) scientific literature relating to the biological effects and toxic effects of talc and other constituents that are present in talc body powder;
- b) the Food, Drug and Cosmetic Act (FDCA) and regulations of the U.S. Food and Drug Administration (FDA) relating to the development and marketing of cosmetic ingredients and finished cosmetic products;
- c) publicly available information on safety assessments of talc and products containing talc; and

d) documents produced during the litigation that are, for example, internal company documents, depositions of company employees, reports of other experts in the litigation, or documents found on public sites.

It should be noted that most of the sources listed above are ones commonly used in my work as a pharmacologist, toxicologist, risk assessor, and United States Food and Drug Administration (FDA) regulatory specialist, including internal company documents that often outline what was known by a manufacturer concerning their product as well as outlining company policies that relate to marketing of cosmetic ingredients and cosmetic finished products in the United States. Additionally, it is important to point out that I have had access to a large database of internal company documents, documents produced as part of the discovery process in the litigation, and that I have performed my own searches of this database as part of my work on the case. In other instances, I have directed others to perform searches on my behalf. Finally, the manufacturers that are relevant to my opinions include Luzenac, a talc ingredient manufacturer that is a part of the company known today as Imerys,² and Johnson & Johnson, the manufacturer of finished talc body powder products, *i.e.*, Johnson's Baby Powder™. Shower to Shower™ and Shimmer™. The other group that is relevant to my opinions in this case is the trade organization for the cosmetics industry in the United States known as the Personal Care Products Council (PCPC), a group that was formerly known as the Cosmetic, Toiletry and Fragrance Association (CTFA).

11. With respect to the methodology employed in forming my opinions for this report and my earlier reports, I used standard and generally accepted methods that apply in all my work as a pharmacologist and toxicologist that is related to assessing the safety of products, both litigation and non-litigation projects. The tool I use for safety assessment is a method known as human health risk assessment. Toxicologists routinely assess risks to human health related to exposure to chemicals in the everyday environment using the risk assessment process. In fact, toxicology is the scientific core of risk assessment. Risk assessment is a methodology that has been

² Since 1989, Imerys Talc America, Inc. ("Imerys") or one of its predecessor companies have supplied talc to Johnson & Johnson for its talcum powder products. These predecessor companies include Cyprus Talc Corporation, Luzenac America, Inc., and Rio Tinto Group. Throughout this report, these entities should be considered synonymous with Imerys.

used for decades by a wide variety of governmental bodies to evaluate the safety of chemicals encountered in the everyday environment and to identify the potential adverse health effects from such chemical exposures. In 1983, the National Research Council (NRC) detailed the steps for risk assessment and described the methodology that is in use today as four basic steps: hazard identification, dose-response assessment, exposure analysis, and characterization of risks (NRC, 1983). As a result, risk assessment is a standard tool used by toxicologists when they are trying to determine if exposure to a chemical(s), or a product, poses a risk to human health. Therefore, as with any project I perform involving safety assessment, I use risk assessment as a tool. The methodology of human health risk assessment is a tool described in the *Reference Manual on Scientific Evidence, Third Edition* (NRC, 2011) which is a resource developed for courts when evaluating methodology used by scientists in litigation projects.

12. The first step in any risk assessment is the one I employed here, *i.e.*, identifying, collecting, reviewing, assessing, and evaluating data from the peer-reviewed scientific literature. This literature is used as the basis of the information employed in the first two steps of the risk assessment, *i.e.*, hazard identification and dose-response assessment. In this case, that literature review involved extensive searching of the published literature that described the effects of talc and talc-based products on some aspect of human health. I used available databases to systematically search the published literature for all relevant literature. The papers I identified described the effects of talc on living organisms, tissues and cells. Some of the resources I identified were textbooks and government documents that provided overviews of the human health risks associated with talc exposure. Also included in my searches were other compounds or chemicals that are constituent parts of talc-based body powders. I had to analyze and evaluate the relevant information. For this process I employed another tool and generally accepted methodology known as a “weight-of-the-evidence” assessment. A weight-of-the-evidence assessment involves evaluating individual studies and determining what the studies describe, when considered as a whole. Therefore, weight-of-the-evidence methods were critical to defining the literature that identified the hazards of talc exposure as well as defining the dose-response relationship between talc exposure and the risk of adverse health effects. The third step in a risk assessment is exposure assessment. As I am not a case-specific expert in this litigation, I was not attempting to define any specific exposure for any specific person in quantitative terms but instead

to use exposure assessment to define the type of information relevant to the product in question, a talc-based body powder. Therefore, exposure assessment involved defining the routes of human exposure that would be relevant for evaluating the risks posed by use of the powders and the type of exposure patterns that have been linked to risks posed by the use of powders. The last step in a risk assessment is risk characterization, a process where the scientist generates some statement about risk. This final step explains the outcome of the risk assessment in terms that explain the potential impact on health of the public, for example.

13. I was trained in the use of these methods as part of my undergraduate, graduate, and postdoctoral work in pharmacology and toxicology, as well as while working as a consultant in human health risk assessment. Weight-of-the-evidence methodology, is used as part of regulatory decision making by regulatory and scientific bodies such as the FDA,³ the U.S. Environmental Protection Agency (EPA),⁴ and the U.S. Occupational Safety and Health Administration (OSHA),⁵ and the World Health Organization (WHO) and the International Agency for Research on Cancer (IARC).⁶ The *Reference Manual on Scientific Evidence* also describes the use of weight-of-the-evidence by experts in the process of evaluating a body of data or studies.⁷

14. At the end of this report is attached a list of the published scientific articles cited throughout this report. Attached to this report as Appendix C is a complete list of all materials that I have reviewed and/or relied upon in forming my opinions in this case. All the opinions expressed in this report are based on a reasonable degree of scientific certainty. I reserve the right to

³ e.g.,

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm079257.pdf>;

<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm074916.pdf>;

<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm079240.pdf>

⁴ e.g., https://www.epa.gov/sites/production/files/2015-06/documents/acephate-103301_2015-06-29_tr0057153.pdf;

<https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=23160&CFID=65932199&CFTOKEN=24176705>;

<https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=71993&CFID=65932266&CFTOKEN=97071893>

⁵ https://www.osha.gov/weightofevidence/woe_guidance.pdf

⁶ http://www.who.int/phe/news/events/international_conference/Session2_DrStraif.pdf

⁷ The *Reference Manual on Scientific Evidence*, 3rd Edition. National Research Council. 2011. Washington, DC: The National Academies Press. <https://doi.org/10.17226/13163>.

supplement and refine my opinions as additional relevant information becomes available. I also reserve the right to review and comment on the reports and testimony of Defendants' experts.

III. Talcum Powder Products: The Regulatory Process

15. Johnson & Johnson talcum powder products entered the marketplace in 1894. At that time, the FDA did not exist and there was no law in place related to any type of product that is currently addressed by FDA regulations. Prompted by a series of food contamination issues, the Pure Food and Drugs Act was passed by Congress and signed into law in 1906 (Janssen 1981). This initial law was enforced by the Agriculture Department's Bureau of Chemistry and prohibited the introduction of "misbranded" and "adulterated" foods, drinks, and drugs into interstate commerce. In 1930, the Bureau of Chemistry became the Food and Drug Administration. In the decades that followed the passage of the 1906 law, scientists involved in administration of the law were confronted with a series of public safety issues that included notably a drug-related tragedy (Sulfanilamide Elixir) and a cosmetic-related tragedy (Lash-Lure). In the case of the cosmetic product, a coal tar-based eyelash dye called Lash Lure caused serious eye injuries that included blindness and one death. Yet, it was the drug-related tragedy, where 107 people died, that purportedly led to passage of Food, Drug & Cosmetic Act (FDCA) in 1938 (Berger and Berger, 2017). Before the passage of the FDCA, there was no US law that addressed cosmetic safety specifically; the FDCA extended regulatory authority to cosmetics for the first time. The provisions of the 1938 Act that brought cosmetics under the purview of the FDA have changed little over the decades, in contrast to the multiple substantive changes in the law as it relates to other FDA-regulated products (*e.g.*, drugs, foods and medical devices).

16. As discussed in a review paper written in 1978 by the Commissioner of Food and Drugs (FDA), Dr. Kennedy, the author describes the process by which regulation of various product types evolved over the decades since 1938 (Kennedy, D. 1978). Dr. Kennedy describes how FDA moved forward over the years toward greater authority over drugs and medical devices, as well as foods, but not with respect to cosmetics. He describes the need for FDA to engage in something he termed "movement backward toward the source", where such actions are ones where FDA works to eliminate a public health threat using its existing statutory and research resources. As he stated in his paper:

“It is only in regard to cosmetics-regulated through the Bureau of Foods- that FDA has been frustrated in the necessary movement backward toward the source. While the Agency is charged with assuring that cosmetics are not harmful under conditions of use and are truthfully packaged and labeled, an anomaly in the Food, Drug, and Cosmetic Act places the burden on FDA to prove harm rather than on industry to prove safety, as is true with drugs and food additives...A study conducted by the General Accounting Office (GAO) pointed out that there is increasing evidence that some cosmetic products and ingredients carry a significant risk of injury to consumers and that, despite such evidence, efforts to regulate cosmetics have been hampered by the lack of adequate legislative authority...FDA’s limited ability to reach back toward the source inhibits the Agency’s ability to carry out risk assessment of cosmetic ingredients.” (see pages 611-612 of Kennedy, 1978).

The regulatory standards for cosmetics have remained essentially unchanged since the 1970’s with some exceptions being: (1) in 1975 the FDA stipulated the need for warning statements on the label of cosmetics products and set forth the standards (March 3, 1975; 21 CFR 740); (2) in 1992 FDA initiated voluntary filing of cosmetic product composition statements for cosmetic products (57 FR 3129, Jan. 28, 1992; 21 CFR 720); (3) in 1974 FDA began voluntary registration of cosmetic manufacturing operations (39 FR 10059, Mar. 15, 1974; 21 CFR 710); and (4) in 1974 FDA required certain specifications for cosmetic labeling (39 FR 10056, Mar. 15, 1974; 21 CFR 701). As stated in 2012 testimony before Congress (CRS, 2012), *“FDA’s authority over cosmetics is less comprehensive than its authority over other FDA-regulated products with regard to GMP; premarket notification, clearance, or approval; testing; and mandatory risk labeling.”* The limitations on FDA authority over cosmetics is important in this case given that the Agency relies on cosmetic manufacturers and ingredient suppliers to ensure that the products marketed are safe for human use.

17. Over the years, the U.S. General Accounting Office (GAO) has been involved in evaluation of cosmetic regulations (GAO, 1978). The mission of the GAO is stated as follows: *“GAO exists to support the Congress in meeting its constitutional responsibilities and to help improve the performance and ensure the accountability of the federal government for the benefit*

of the American people.”⁸ In its 1978 report, the GAO provided some important observations and suggestions on how to improve the process for protecting public health. The GAO reached the following conclusions in 1978 regarding cosmetic regulations:

“In spite of the significant risk of injury to consumers, the Food and Drug Administration (FDA) does not have an effective program for regulating cosmetics. The act does not authorize FDA to require manufacturers to register their plants or products, file data on ingredients, file reports of cosmetic-related injuries, or test their products for safety. Also, exemptions in the act do not permit effective regulation of coal tar hair dyes. FDA has not effectively used its existing authority. For example, it has not inspected most manufacturers' plants or sampled products for compliance with the act; it has established regulations governing the use of only 11 ingredients used in cosmetics; the safety of about 25 color additives has not been established; and it has had difficulty developing appropriate tests to be used by manufacturers in evaluating safety.”

The overall conclusion reached is reflected in the title of the report: *“Lack of Authority Hampers Attempts to Increase Cosmetic Safety”*. The GAO also made recommendations that were stated as follows:

“The Congress should authorize the Food and Drug Administration to require cosmetic manufacturers to prove the safety of their products. Because the agency does not have enough authority to effectively regulate cosmetics, products are being marketed which may pose a hazard to consumers. About 125 ingredients available for use in cosmetics are suspected of causing cancer, and about 25 are suspected of causing birth defects. Although many of the reported adverse effects have not been verified, 30 of the ingredients are known to cause cancer in humans or animals or contain impurities known to cause cancer. The ability of these ingredients to cause toxic effects through cosmetic use has not been determined. Manufacturers do not have to determine the safety of their products before selling them or tell the Food and Drug Administration what products they are selling and what ingredients are used in them. Many manufacturers have not voluntarily given such Information to the agency. As a result, a hazardous cosmetic can be marketed until the

⁸ <https://www.gao.gov/dsp/3mission.html>

Food and Drug Administration obtains information to prove that the product may be injurious to users."

The discussion and findings by the GAO in 1978 are important context for understanding the responsibilities of cosmetic manufacturers and suppliers of cosmetic ingredients, such as Johnson & Johnson and Imerys, with respect to talcum powder products. The lack of FDA authority in key areas of cosmetic regulations that existed in the past, and exist even today, means that companies that market cosmetic products and ingredients must ensure that the products they sell are safe for use before they are marketed and continue to be safe for use as new scientific information becomes available.

18. With this historical context in mind, at issue in this litigation are cosmetic products known as talcum powder products. As mentioned above, current law does not require that cosmetics or cosmetic ingredients have FDA approval before they enter the market.⁹ This is true despite recent changes to cosmetic law in 2022 (the Modernization of Cosmetics Regulation Act of 2022 known as MoCRA).¹⁰ Once cosmetic ingredients and products are marketed and placed into interstate commerce, the two important laws that pertain to the industry include the FDCA and the Fair Packaging and Labeling Act (FPLA). The FDCA defines cosmetics by their intended use, in the same way that other products (*i.e.*, drugs, device, foods, *etc.*) are regulated according to their intended use. A cosmetic is defined as follows: *"The term cosmetic means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap."* (FDCA Section 201(i)). Among the products included in this definition are skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup, cleansing shampoos, permanent waves, hair colors, and deodorants, as well as any ingredient intended for use as a component of a cosmetic product. The FPLA, enacted in 1967,

⁹ <https://www.fda.gov/cosmetics/guidanceregulation/lawsregulations/ucm074162.htm>

¹⁰ <https://www.fda.gov/cosmetics/cosmetics-laws-regulations/modernization-cosmetics-regulation-act-2022-mocra>; it should be noted that FDA has not yet codified the new provisions of MoCRA in the CFR but has issued some guidance such as the recent *Compliance Policy for Cosmetic Product Facility Registration and Cosmetic Product Listing* (November 2023) and the *Guidance for Industry: Registration and Listing of Cosmetic Product Facilities and Products* (December 2023).

directed the Federal Trade Commission (FTC) and the FDA to issue regulations requiring that "*consumer commodities*" be labeled to disclose net contents, identity of commodity, and name and place of business of the product's manufacturer, packer, or distributor.¹¹ In the case of cosmetics, the FDA was given responsibility for administering the law and for issuing regulations regarding labeling for foods, drugs, devices, and cosmetics.

19. Since the FDCA does not require that cosmetics undergo any type of approval by FDA before marketing, the focus of the regulations that have existed since passage of the law in 1938 has been to ensure that cosmetics are not "*adulterated*" and "*misbranded*". The term "*adulterated*" with respect to cosmetics means that the product or an ingredient is known to pose a risk to human health, or the product is known to be unsanitary, or the product contains a prohibited ingredient, or the product is manufactured under unsanitary conditions (Jackson, 1995). The term "*misbranded*" means that the cosmetic product has false or misleading labeling, that the labeling fails to state information required by FDA (*i.e.*, name of product, net weight or amount of product, name of the company marketing the product, ingredients listed in descending order of amount, and any warnings about safety issues that the company is aware exist), or that the product packaging is misleading to the consumer in some way in terms of what it contains. FDA has published guidance on how to label cosmetic products.¹²

20. Unlike human drug products, both prescription drug products and those sold over-the-counter (OTC), there is no risk-benefit assessment performed as a part of a decision to allow a cosmetic product to be marketed. Cosmetics are not recognized to provide any health benefit, and, as a result, any significant health risks or concerns are unacceptable for such products. In the case of a drug, both FDA and the public understand that in some cases risks can be acceptable so long as there is some benefit assessment that outweighs that risk assessment. There are some products that are both cosmetics and drugs, and in those cases, the manufacturer must comply with both cosmetic and drug regulations.

¹¹ <https://www.ftc.gov/enforcement/rules/rulemaking-regulatory-reform-proceedings/fair-packaging-labeling-act>

¹² <http://www.fda.gov/downloads/Cosmetics/Labeling/UCM391202.pdf>

21. It is the cosmetic manufacturer that is responsible for ensuring that its product and its ingredients are safe for use. The cosmetic ingredient supplier also has a duty to provide warnings related to the safety of the ingredients supplied to finished product manufacturers (*Federal Register* 40(42) March 3, 1975). The FDA does no testing itself. Instead, the FDA relies on companies to conduct all testing to ensure that the finished product, and its ingredients, are safe for human use. Therefore, as is stated by FDA:

*“Companies and individuals who manufacture or market cosmetics have a legal responsibility to ensure the safety of their products. Neither the law nor FDA regulations require specific tests to demonstrate the safety of individual products or ingredients. The law also does not require cosmetic companies to share their safety information with FDA.”*¹³

As a result, manufacturers have a duty to conduct whatever testing is necessary to ensure the safety of their products and ingredients. This has been confirmed in recent FDA statements as well.¹⁴

22. Another aspect of the FDA regulations pertaining to cosmetics that needs to be discussed is the standard for establishing a warning that would be placed on the labeling of a cosmetic product. It is important to realize that the standard for placing a warning on a cosmetic product is very different than the standard applied to products such as drugs. The standard applied to human prescription drug products in the US is as follows (21 CFR 201.57):

*“The labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; **a causal relationship need not have been definitely established.**” [emphasis added]*

In the case of cosmetic products and their ingredients, however, the warning standard is as follows: (21 CFR 740.1):

740.1 Establishment of warning statements

*(a) The label of **a cosmetic product shall bear a warning statement** whenever necessary or appropriate to prevent a health hazard that **may be associated** with the product. [emphasis added]*

¹³ <http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074162.htm>

¹⁴ <https://www.fda.gov/cosmetics/cosmetics-laws-regulations/modernization-cosmetics-regulation-act-2022-mocra>

This means that, unlike drugs, cosmetics are expected to carry warnings based on a standard of a possibility of health hazard, not on having evidence of a causal association between a health effect and the cosmetic product or ingredient. Not requiring proof of a cause-and-effect relationship is consistent with FDA's policy with drugs where causation does not need to have been proven before a warning may be placed on a drug product (see 21 CFR 201.57(c)). This issue is important in the current case involving talc cosmetic products and cancer risk because of the large body of evidence that developed over the decades providing evidence of increased risk of cancer with perineal use of talc body powder products---an important health hazard. It also is important to note that use of the term "hazard" rather than "risk" by FDA in its cosmetic labeling standard means that the likelihood of the harm being discussed (*i.e.*, cancer) does not need to be understood; it only requires that the inherent properties of the substance indicate the substance is capable of harm. Based upon the totality of the evidence reviewed there is **more than a possibility of a human health hazard**; these issues will be discussed in more detail below.

23. In the case of cosmetics, this reliance on industry for product safety assessments is especially important given that there is no Center for Cosmetics at FDA. Instead, the cosmetics regulations are enforced by the Office of Colors and Cosmetics that is within the Center for Food Safety and Applied Nutrition (CFSAN). As FDA has admitted, although the FDA has ways to monitor cosmetic products, available safety information is often limited (<http://www.fda.gov/AboutFDA/Transparency/Basics/ucm262353.htm>). The methods available to FDA for monitoring cosmetic products include: (1) voluntary cosmetic registration program (VCRP); (2) inspections of facilities that voluntarily register with FDA; (3) surveys of product; (4) information conveyed in Cosmetic Ingredient Review (CIR) expert panel reviews;¹⁵ and (5) spontaneous reports from consumers. In the case of the VCRP program, companies are not legally required to tell FDA anything about their products and the type of safety data that exists. Inspection of facilities is also not legally mandated, and, as acknowledged by FDA, due to limited resources *"only a few establishments are inspected each year and just a fraction of imports are physically examined"*. Similarly, FDA has conducted surveys of marketed products by buying them and then

¹⁵ Although the FDA has access to, and can evaluate, the findings of a CIR review, such as the review for talc, the FDA does not adopt CIR findings. (See deposition testimony and exhibits of Dr. Linda Loretz dated October 2, 2018)

examining them. This has mainly been done after some problem has been identified. The CIR panel process is an industry-funded process that typically is undertaken based on some impetus for review that is initiated within government, industry or the public. The spontaneous reporting by consumers to FDA is not required by law, and many consumers are unaware of the existence of the process for cosmetics.

24. There are some important constraints on FDA's authority as it relates to cosmetics. For example, any product recall of a cosmetic for a safety reason must be a voluntary action initiated by manufacturers or distributors to remove products from the market that may pose a hazard, that are marketed in a deceptive manner, or that are defective in some way (21 CFR 7.40(a)).¹⁶ FDA can request such recalls but cannot require such recalls.

25. Unlike products such as drugs, devices and even foods, cosmetic manufacturers are not required to register the facilities where the cosmetics are manufactured.¹⁷ This means that although FDA has the authority to inspect such facilities, unless the facility is registered, no inspections are made. In circumstances where an issue of product contamination or adulteration comes to light, FDA does have the authority to go and inspect facilities. This means that FDA is in the role of responding to problems, not preventing problems before they occur. Again, this is very different than the role FDA plays for other types of products.

26. In 1997, FDA issued guidance to industry related to Good Manufacturing Practices (GMPs) for cosmetics.¹⁸ The guidance has been updated as late as 2013. This guidance is non-binding but does lay out FDA's thinking in terms of how to properly manufacture, ensuring that cosmetics and their ingredients are safe for use in humans. This situation is unlike other FDA regulated products where there are mandatory GMP regulations that are actively enforced by FDA (*i.e.*, in the case of drugs, devices, and even foods).

¹⁶<https://www.fda.gov/cosmetics/complianceenforcement/recallsalerts/ucm173559.htm>

¹⁷ <https://www.fda.gov/cosmetics/registrationprogram/default.htm>

¹⁸ <http://www.fda.gov/Cosmetics/GuidanceRegulation/GuidanceDocuments/ucm353046.htm>

27. Based on the general lack of regulatory oversight for cosmetics, it cannot be assumed that all marketed cosmetic ingredients and products are safe for human use. Additionally, it is likely that the public is unaware that FDA has strict limitations on its ability to ensure protection of public health when it comes to cosmetic products. With these regulatory limitations in mind, the chemical components of talc body powders and their hazards were considered and are discussed below with respect to the health hazards linked to the chemical components, the evidence linking cancer with exposure to chemical components of talcum powder products, and the need to provide warnings to consumers regarding health risks that may be linked to the chemical components of talcum powder products.

IV. Chemical Components of Talcum Powder Products and Their Hazards

28. The chemical nature of talc has been reviewed (*e.g.*, USEPA, 1992; IARC, 2010). Talc (CAS No. 14807-96-6), or magnesium silicate monohydrate, is a naturally occurring hydrous magnesium silicate compound with the chemical formula $3\text{MgO} \cdot 4\text{SiO}_2$. Like other minerals, talc can be classified by its structure, which consists of water molecules trapped between silicate sheets. This structure imparts the “feel” to talc, which is often referred to as slippery on the skin. Talc crystals are formed when these sheets stack upon each other. Talc can exist in non-plate forms as well. For example, asbestiform talc exists in nature, where asbestiform means the talc is in the shape of a fiber similar to the structure of asbestos. IARC in its 2010 Monograph on talc, provides a description of talc particles as follows: “*Talc particles are normally plate-like. When viewed under the microscope in bulk samples or on air filters, they may appear to be fibres and have been identified as such. Talc may also form as true mineral fibres that are asbestiform; asbestiform describes the pattern of growth of a mineral that is referred to as a ‘habit’. Asbestiform talc fibres are very long and thin and occur in parallel bundles that are easily separated from each other by hand pressure.*” (IARC, 2010 at 277). The IARC Monograph also describes asbestiform talc as not the same as talc that contains asbestos; asbestiform talc is a fibrous form of talc itself (IARC, 2010 at 406). In this report the term fibrous talc may be used to differentiate this talc powder constituent from platy talc. It is important to make such distinctions because the structure of the talc particles, platy or fibrous, and the size of the talc particles, influence the toxicity potential of the talc powder.

29. As a mineral, talc is mined in countries around the world, including in the United States. Talc can be prepared to various specifications depending on the purity desired. Talcum powder products such as the ones manufactured and sold by Imerys and Johnson & Johnson were mainly platy talc but varied in their level of purity. In other words, talc powders were not 100% platy talc but contained levels of other co-occurring compounds such as talc containing asbestiform fibers (e.g., talc occurring in a fibrous habit), asbestos, nickel, chromium, and cobalt. These talc components are present in nature and are found in processed talcum powders. As a result, the purity of talcum powder products is an issue important to any safety assessment. Notably talcum powder products manufactured decades ago were well known to contain asbestos as an impurity (EPA, 1992; IARC 2010; IARC, 2012). Contemporary cosmetic grade talcum powder products also have been shown to contain detectable levels of impurities that have included asbestos (Gordon *et al.* 2014). In 2009 and 2010, the FDA performed a survey where they examined 27 samples of cosmetic-grade raw talc and 34 talc-based products, including seven talc samples from Rio Tinto/Luzenac, one bottle of Shower to Shower, and one bottle of Johnson's Baby Powder, for the presence of asbestos.¹⁹ FDA reported no detection of asbestos in the sample tested. However, as discussed by FDA: *"The results were limited, however, by the fact that only four talc suppliers submitted samples and by the number of products tested. For these reasons, while FDA finds these results informative, they do not prove that most or all talc or talc-containing cosmetic products currently marketed in the United States are likely to be free of asbestos contamination."* Additional FDA testing for the presence of asbestos in talc body powder products has occurred. In October of 2019, Johnson & Johnson recalled a lot of its talcum body powder based on FDA finding asbestos and talc fibers in one of two lots that were tested.²⁰ FDA also tested samples of talc-based cosmetic products for the presence of asbestos in 2020-2021 but none of the samples tested were Johnson & Johnson body powder products.²¹ In 2022, FDA again tested talc-containing cosmetics for the presence of asbestos but again, no Johnson & Johnson body powder products were tested.²² It is important to note that in addition to actions taken by the FDA, the U.S. Environmental Protection Agency (EPA) has recognized the potential human health hazard posed

¹⁹ <http://www.fda.gov/Cosmetics/ProductsIngredients/Ingredients/ucm293184.htm>

²⁰ <https://www.fda.gov/cosmetics/cosmetics-recalls-alerts/fda-advises-consumers-stop-using-certain-cosmetic-products>; <https://www.fda.gov/media/135911/download?attachment>

²¹ <https://www.fda.gov/media/153415/download?attachment>

²² <https://www.fda.gov/media/163572/download?attachment>

by the presence of asbestos as an impurity in talc. They published a Proposed Rule in May 2022 concerning a planned expansion of their risk evaluation and risk management activities related to asbestos exposure; the Rule was made Final in July 2023 (Federal Register Vol. 88, No. 141, July 24, 2023 pages 47782-47806).²³

30. I considered the FDA testing findings in light of the disclaimer related to the 2009-2010 data, which acknowledge the limited sample size, as well as the fact that one of two lots of Johnson & Johnson baby powder tested in 2019 was positive for asbestos, and the fact that baby powder samples were not part of the testing program at FDA in 2020, 2021 and 2022. As discussed in detail below, a review of internal company documents reveals that Imerys and Johnson & Johnson were aware that talcum powder products contained detectable levels of other toxic compounds that included but were not limited to fibrous talc, asbestos, silica, chromium, nickel, and cobalt. There was one additional component of talcum powder products manufactured and sold by Johnson & Johnson, a fragrance component that contained many different chemicals (discussed below as well). Therefore, women using talcum powder products for genital dusting, or for application anywhere on the body, were exposed to a mixture of chemicals, not 100% pure platy talc. As a result, when performing a talcum powder product safety assessment, studies that describe talc products of varying purity levels were relevant to the assessment.

31. In the published medical literature, there is often discussion of talc using terms such as fibrous talc, asbestiform talc, non-asbestiform talc, or tremolite. Before discussing the literature on the toxicity of talcum powder products and its associated constituents it is useful to provide some background on the terminology of the mineral components of talcum powder products. As mentioned above, talc is one of a group of hydrous magnesium silicate minerals; its chemical formula is $\text{Mg}_3\text{Si}_4\text{O}_{10}(\text{OH})_2$. Talc can occur as platy sheets of talc but also forms bundles of fibers (*i.e.*, occur in an asbestiform habit), which consist of a group of individual elongated crystals. Asbestos is also a hydrous magnesium silicate mineral and has a chemical formula of $\text{Mg}_3\text{Si}_2\text{O}_5(\text{OH})_4$. Like the term “talc”, asbestos is the generic designation for a group of naturally occurring mineral silicate compounds that occur as fibers, either serpentine or amphibole fibers. The asbestos forms include the serpentine mineral chrysotile, and five amphibole minerals

²³ <https://www.govinfo.gov/content/pkg/FR-2022-05-06/pdf/2022-09533.pdf>

(actinolite, amosite, anthophyllite, crocidolite, and tremolite) (IARC, 2012). Chrysotile, lizardite, and antigorite are the three principal serpentine silicate minerals, but only chrysotile occurs in the asbestiform habit (USGS, 2001). In the amphibole series, amosite and crocidolite occur only in the asbestiform habit, while tremolite, actinolite and anthophyllite occur in both asbestiform and non-asbestiform habits. As discussed in older published literature, fibrous talc was often a term used to refer to any form of fiber in talc, including asbestos (Rohl *et al.* 1974). As a result, in this report, care was taken to use these terms when referring to the detection of fibers: asbestos, non-asbestiform talc (platy talc), and talc containing asbestiform fibers (fibrous talc). My analysis is consistent with how IARC considered the cancer risks of different forms of talc (IARC, 2010; IARC, 2012).

32. Since talc occurs as a particle in nature, the biological effects of talc, including its adverse effects or toxic effects, are related to both its chemical composition and its physical structure. This is a general principle of toxicology that relates to tissue contact with chemical particles.²⁴ The biological effects and toxicology of talc have been reviewed (IARC, 1987; USEPA, 1992; IARC, 2010; Health Canada, 2021). The types of effects observed depend, in part, on the route of exposure. As a mineral, talc has the propensity to produce an irritant and inflammatory response at sites of exposure (reviewed in EPA, 1992; discussed in more detail below). It is the irritant and inflammatory properties of the mineral that the scientific literature indicates underlie many of the human health risks associated with talc exposure (as reviewed in IARC, 1987; EPA, 1992; IARC, 2010; IARC 2012; discussed in more detail below). The presence of fibers in talc is important because exposure to fibers is known to cause adverse biological effects in cells and tissue. This is driven in part by the fact that the tissue response to a fiber as compared to a particle is affected by the ability of immune cells to engulf the fiber (Fubini and Fenoglio, 2007). If the fiber is long, immune cells cannot totally engulf the compound and remove the foreign material from the tissue. As a result, there are similarities in the potential adverse effects that are associated with any fibrous mineral, both talc and asbestos.

33. Given that talc used to manufacture body powders has the potential to be a mixture of toxic compounds, it is important to understand the constituents of commercially available

²⁴ http://ehs.unl.edu/documents/tox_exposure_guidelines.pdf

talcum powder products manufactured and sold by Imerys and Johnson & Johnson. Johnson & Johnson was aware that asbestos or asbestiform fibers were present in talc that was mined for talcum powder products (*e.g.*, JNJ000251888). When commercially available talcum powder products have been analyzed, including powders sold by Johnson & Johnson, the data has shown that the powders contain variable levels of fibers, including fibrous talc as well as fibers that were stated to be asbestos (*e.g.*, IARC, 2012; Paoletti *et al.* 1984; Blount, 1991; Mattenklott *et al.* 2007; Moon *et al.* 2011; Gordon *et al.* 2014; Anderson *et al.* 2017; Rohl *et al.* 1976; Pooley and Rowlands, 1975; Blejer and Arlon, 1973; Cralley, *et al.* 1968; Millman, N. 1947; JNJ000025132; IMERYS205540-554; IMERYS136824; IMERYS265938-993; IMERYS245144; JNJ000375389-390; IMERYS240376-378; IMERYS240406; IMERYS213431-433; JNJNL61_000052427; JNJNL61_000042576; IMERYS138505-511; IMERYS100130-150; JNJMX68_000004996-5031; JNJTALC000301172-1179; JNJ000264653-4655; JNJNL61_000033289-3292; JNJTALC000293589-591; JNJTALC000292656-657; IMERYS051370-374; IMERYS219720-722; JNJ000062359-363; JNJ000062436; JNJ000063951; JNJ000064544; JNJ000065264-266; JNJ000277941-943; JNJ000314315-316; JNJ000314406-414; JNJAZ55_000000905-948; JNJAZ55_000004563; JNJMX68_000003728; JNJMX68_000013019-020; JNJNL61_000079334; JNJMX68_000020276-282; JNJ000231304-318; IMERYS-MDL-AB_0006980; IMERYS 210136). In more recent work related to this litigation, scientists have found that samples of Johnson & Johnson body powder products that were examined contained fibrous talc (report by Longo and Rigler dated April 28, 2017²⁵ where 8 of 11 samples contained fibers; report by Longo and Rigler dated August 2, 2017, ²⁶ where 15 of 30 talc samples contained fibrous talc and 17 of 30 samples contained fibrous amphiboles). Dr. Longo's testing of talcum powder samples produced in the MDL revealed that 37 of 56 samples contained asbestos and 41 of 42 samples tested were observed to contain asbestiform talc (report of Longo and Rigler dated February 1, 2019²⁷). Although companies have claimed that talcum powder products manufactured after the mid-1970's were free of asbestos, asbestos fibers have been found in products in the marketplace after that time (*e.g.*, Paoletti *et al.* 1984; Blount, 1991;

²⁵ The report is entitled "Analysis Report: MAS Project # 14-1683 Johnson's Baby Powder Sample Set.

²⁶ The report is entitled "Analysis of Johnson & Johnson Baby Powder and Valiant Shower to Shower Products for Amphibole (Tremolite) Asbestos".

²⁷ "The Analysis of Johnson & Johnson's Historical Product Containers and Imerys' Historical Railroad Car Samples from the 1960s to the Early 2000s for Amphibole Asbestos, 2nd Supplemental Report, Longo & Rigler, MAS Analytical Services, February 1, 2019.

Mattenklott *et al.* 2007; Moon *et al.* 2011; Anderson *et al.* 2017; Egilman and Steffen, 2018; February 16, 2018 report of Longo and Rigler;²⁸ IMERYYS095086-087; IMERYYS136824; IMERYYS245144; JNJ000375389-390; IMERYYS213431-433; JNJNL61_000014431-14437; IMERYYS219720-722). These published scientific studies, internal testing documents, and testing results by Longo and Rigler show that asbestos has been consistently present in Johnson & Johnson's talcum powder products since the mid-1950's and certainly after the 1970's when the defendants represented that asbestos had been eliminated from talcum powder products (additional support found within the exhibits and deposition testimony of Ms. Julie Pier, dated September 12, 2018; and Dr. John Hopkins, dated August 16 & 17, 2018; October 17, 2018, and November 5, 2018). The presence of asbestos was evidenced before the 1970's and continues to be to be found in test results. It is important to note that talc containing asbestiform fibers was classified in 1986 as a known human carcinogen (IARC, 1987, 2010, 2012). In IARC's most recent findings regarding asbestos and cancer (IARC, 2012) scientists explicitly stated that its findings on asbestos and cancer risk applied equally to asbestiform talc (IARC, 2012 at 219). This makes clear that IARC has classified fibrous talc as a known human carcinogen. Other regulatory authorities have addressed the cancer risk associated with fibrous talc. For example, talc containing asbestiform fibers was listed by the State of California (PROP 65) in April 1990 as a chemical "*known to the State to cause cancer*".²⁹ Given that the National Institute for Occupational Safety and Health (NIOSH) has stated that there is no safe level of asbestos exposure (NIOSH, 1980), human exposure to even very low levels of asbestos increase the risk of toxic effects including cancer, a finding that also could be applied to similar fibers, such as fibrous talc.

34. With respect to asbestos as a constituent of talcum powder products, it had been known at least by the 1930's that asbestos exposure caused lung disease (*e.g.*, Cooke, 1927; Oliver, 1927; Seiler, 1928; Wood, 1929; Merewether and Price, 1930; Merewether, 1930; Gloyne, 1935). As one author described the issue of asbestos exposure and lung disease, "***widespread recognition of asbestosis dates from the work of Merewether and Price in 1930 [emphasis added]***" (Hourihane and McCaughey, 1966). Additionally, it was known at least by the 1950's that asbestos exposure

²⁸ The report is entitled "TEM Analysis of Historical 1978 Johnson's Baby Powder Sample for Amphibole Asbestos".

²⁹ <https://oehha.ca.gov/media/downloads/crn/p65list052518.pdf>

could cause lung cancer (*e.g.*, Gloyne, 1935; Doll, 1955; Selikoff *et al.* 1964). Additionally, some studies have reported an increased risk of ovarian cancer in women exposed to asbestos (*e.g.*, Keal *et al.* 1960; Graham and Graham, 1967; Newhouse *et al.* 1972; Acheson *et al.* 1982; Wignall and Fox, 1982; Newhouse *et al.* 1985; Tarchi *et al.* 1994; Bulbulyan *et al.* 1999; Germani *et al.* 1999; Magnani *et al.* 2008; Bunderson-Schelvan *et al.* 2011; Camargo *et al.* 2011; Wang *et al.* 2013; Ferrante *et al.* 2017; Kim *et al.* 2024). Regulatory authorities world-wide have identified asbestos as a known human carcinogen (*i.e.*, IARC, 1987; IARC, 2012; ATSDR, 2001; NTP, 2016; Canada³⁰; European Union³¹; Australia³²). Given the well-known toxic effects and human health risks associated with asbestos, the presence of asbestos fibers in talcum powder products is a significant risk to human health.

35. There is a fragrance component added to all Johnson & Johnson talcum powder products. In the document entitled “*Defendant Johnson & Johnson Consumer Inc.’s Supplemental Answer to Plaintiffs’ Second Set of Interrogatories No. 19*” dated December 21, 2017, Johnson & Johnson provided a list of fragrance chemicals that are added to Johnson’s Baby Powder® products and a list of chemicals that had been added to Johnson & Johnson’s Shower-To-Shower® products. Over 50 fragrance chemicals were listed as having been added to the Shower-To-Shower products while more than 130 fragrance chemicals were listed as being currently used in Johnson’s Baby Powder. This means that any bottle of talcum powder sold to consumers contained many different chemicals, not simply platy talc. It should be noted that recent changes to the Johnson & Johnson website provide disclosure to consumers of what is claimed to be “100%” of their fragrance ingredients.³³ The list on the website, however, is not the same as the list provided in the 2017 documents discussed above, and the website also fails to provide information on the fragrance chemicals used in the past. Both sources of information, the 2017 document produced by Johnson & Johnson and their updated website, fail to provide specific information on the amount of each chemical component in the fragrance component of either Johnson’s Baby Powder or Shower-To-Shower.

³⁰ <https://www.canada.ca/en/health-canada/services/air-quality/indoor-air-contaminants/health-risks-asbestos.html>

³¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM%3Aem0032>

³² <https://www.safeworkaustralia.gov.au/asbestos>

³³ <https://www.johnsonsbaby.com/our-mission/scents-fragrance>

36. A review of the chemicals listed in the 2017 document reveals that, in many cases, the compounds listed are known to have toxic properties. In fact, of the fragrance chemicals listed, several have been associated with potential carcinogenic activity. These include ethenyl benzene, also known as styrene, and *p*-cresol (4-methylphenol). Styrene is a compound that has been classified by the National Toxicology Program (NTP) as “reasonably anticipated to be a human carcinogen”³⁴, and classified by IARC as a 2A carcinogen (probable human carcinogen)³⁵. In the case of *p*-cresol, EPA has determined that it is “possibly carcinogenic to humans”.³⁶ Other chemicals listed as being a part of the fragrance component of Johnson & Johnson talc body powders have been reviewed by IARC for cancer potential (coumarin, eugenol, d-limonene; all given a Category 3 classification of “not classifiable”)³⁷. A cancer risk, however, is not the only human health risk linked to the numerous fragrance chemicals present in Johnson & Johnson talc body powder products. Even a cursory search of the scientific information available on either non-governmental sites or regulatory authority sites³⁸ shows that most of the chemicals are known individually to have irritant properties and/or inflammatory properties when in contact with cells and tissues. Of the more than 100 chemicals included in the 2017 list of fragrance ingredients, over 70% are compounds that have been linked with some level of irritant hazard to tissues (skin, eye, mucous membranes; see Appendix D to this report; report of Dr. Michael Crowley). The issue of irritant properties will be discussed below as it relates to carcinogenesis and mechanisms for cancer linked to talc and the chemical components of talc. Yet, consumers have never been provided with information that any of the ingredients in the Johnson & Johnson fragrance posed a potential human health risk.

37. In addition to the presence of asbestos in talcum powder products and the presence of dozens of fragrance chemicals, evidence shows that the products manufactured by Imerys and sold by Johnson & Johnson contained detectable levels of heavy metals (*e.g.*, JNJ000245268-274; JNJMX68_000004996-5031; IMERYS223869-883; IMERYS265938-993; IMERYS194090-095;

³⁴ <https://ntp.niehs.nih.gov/ntp/roc/content/profiles/styrene.pdf>;

<https://www.atsdr.cdc.gov/substances/toxsubstance.asp?toxid=74>

³⁵ <https://monographs.iarc.fr/list-of-classifications-volumes/>

³⁶ <https://www.atsdr.cdc.gov/substances/toxsubstance.asp?toxid=196>

³⁷ <https://monographs.iarc.fr/wp-content/uploads/2018/06/ClassificationsAlphaOrder.pdf>

³⁸ Searches of publicly available databases were performed including TOXNET, PUBCHEM, HSDB, The Good Scents Company (www.thegoodscentscompany.com), the Environmental Working Group (<https://www.ewg.org/>), cosmeticsinfo.org (PCPC sponsored site), and the Cosmetic Ingredient Review (<https://www.cir-safety.org>).

IMERYS032928; IMERYS094601; IMERYS053387-88; IMERYS098115-116; IMERYS219720-722; IMERYS304036; IMERYS-A_0015663; JNJ000265171; JNJTALC000869376; JNJ000025132; JNJ000347962-963; P-68; exhibits and deposition testimony of Ms. Julie Pier dated 9/12/2018; Cralley *et al.* 1968; Pooley and Rowlands, 1975; Rohl *et al.* 1976; Gondal *et al.* 2012; Rehman *et al.* 2013) as well as levels of silica (JNJ000260573 through 574; JNJ000260570; JNJ000260709). The levels of heavy metals have varied across different processed lots of talcum powders, but internal company documents show that certain heavy metals have been repeatedly detected, such as chromium (Cr), cobalt (Co), and nickel (Ni). These heavy metals are known to be toxic to human cells and tissues. Some of these heavy metals are known to be carcinogenic in animals and/or humans. Chromium (Cr) and nickel (Ni) have been classified as “*known human carcinogens*” by IARC³⁹. Cobalt (Co) has been classified by IARC as Group 2B, or “*possibly carcinogenic to humans*”.⁴⁰ The NTP has listed chromium (Cr) and nickel (Ni) as “*known to be human carcinogens*”, while cobalt is listed as “*reasonably anticipated to be human carcinogens*”.⁴¹ With respect to silica, levels also appeared to vary across lots. Like asbestos and fibrous talc, silica is a known human carcinogen (IARC, 1997; IARC, 2012; NTP, 1991).

38. Focusing now on talc itself as a toxic compound, a review of the scientific literature reveals that in many cases, the compound being tested or discussed is usually described simply as talc, with no description of the purity or physical state of the compound (fibrous or platy). In the following discussion of the literature that relates to the toxicity of talc, I will mention the specific type of talc (*i.e.*, mined talc, milled talc, fibrous talc, talc of certain purity levels, cosmetic grade talc, *etc.*), if reported.

39. A review of the published scientific literature shows that the human health hazards associated with exposure to talc dust has been known for decades, well before the 1970’s. In fact, as far back as the first half of the 20th century (before 1950), scientists had discovered that:

³⁹ <https://monographs.iarc.fr/wp-content/uploads/2018/06/ClassificationsAlphaOrder.pdf>

⁴⁰ <https://monographs.iarc.fr/wp-content/uploads/2018/06/ClassificationsAlphaOrder.pdf>

⁴¹ https://ntp.niehs.nih.gov/ntp/roc/content/listed_substances_508.pdf

- talc particles produced adverse tissue reactions in cells or tissues, and in humans and animals (*e.g.*, tremolite talc: Dreessen, 1933; Miller and Sayers, 1936; Greenburg, 1947; mining talc: Porro *et al.* 1942; Porro and Levine, 1946; Schepers and Durkan, 1955; industrial grade talc: Schulz and Williams, 1942; McLaughlin *et al.* 1949; Jaques and Benirschke, 1952; Sax, 1957; cosmetic grade talc: Roberts, 1947; Saxen and Tuovinen, 1947; Eiseman *et al.* 1947; U.S. Patent No. 2,621,333 filed June 27, 1947; Eberl *et al.* 1948; Graham and Jenkins, 1952; U.S. Patent No. 2,626,257 filed May 21, 1952 by Johnson & Johnson; Cless and Anger, 1954; Creery *et al.* 1957; Sax, 1957);
- exposure to talc dusts in an occupational setting was linked to an increased risk of lung disease, including cancer (*e.g.*, tremolite talc: Dreessen, 1933; Greenburg, 1947; mining talc: Dreessen and Dalla Valle, 1935; Porro *et al.* 1942; Porro and Levine, 1946; Kleinfeld *et al.* 1955; Schepers and Durkan, 1955; industrial grade talc: McLaughlin *et al.* 1949; Hogue and Mallette, 1949; Jaques and Benirschke, 1952; Mann and Deasy, 1954; Seeler *et al.* 1959; cosmetic grade talc: Millman, 1947);
- the risks associated with occupational exposures to talc were higher when fibrous forms of magnesium silicate minerals (talc as well as asbestos) were present (*e.g.*, Dreessen and Dalla Valle, 1935; Schulz and Williams, 1942; Saxen and Tuovinen, 1947; Millman, 1947; Greenburg, 1947; Hogue and Mallette, 1949; Schepers and Durkan, 1955); and
- exposure to cosmetic grade talcum powders themselves were associated with adverse tissue responses and adverse human health effects, including cancer in some cases (*e.g.*, Roberts, 1947; Greenburg, 1947; Eiseman *et al.* 1947; U.S. Patent 2,621,333; Eberl, 1948; Graham and Jenkins, 1952; U.S. Patent No. 2,626,257; Cless and Anger, 1954; Creery *et al.* 1957).

40. Upon review of the scientific literature available since 1960, the evidence has continued to accumulate showing that:

- talc has adverse effects in cells, tissues, animals and humans (*e.g.*, cosmetic grade talc: Molnar *et al.* 1962; Blumel *et al.* 1962; Jenkins, 1963; Tye *et al.* 1966; Trautwein and Helmboldt, 1967; Migaki and Garner, 1969; Merliss, 1971; Pott and Friedrichs, 1972; Wagner *et al.* 1975; Stenback and Rowland, 1978; Kaiser *et al.* 1982; Davies *et al.*

- 1983; Hamilton *et al.* 1984; Stenback *et al.* 1986; Pelling and Evans, 1986; NTP, 1993; Hamilton *et al.* 2001; Buz'Zard and Lau, 2007; Shukla *et al.* 2009; Shim *et al.* 2015; Fletcher *et al.* 2018; Fletcher and Saed, 2018; Fletcher *et al.* 2019; Mandarino *et al.* 2020, Harper *et al.* 2021; Emi *et al.* 2021, ; mining or milling talc: Kleinfeld *et al.* 1963; Beck *et al.* 1987; unspecified: Henderson *et al.* 1971; Blejer and Arlon, 1973; Pott *et al.* 1974; Henderson *et al.* 1979; Abraham and McEuen, 1986);
- exposure to talc dusts in an occupational setting was linked to an increased risk of lung disease, including cancer (*e.g.*, mining or milling talc: Kleinfeld *et al.* 1963; Kleinfeld *et al.* 1964; Kleinfeld *et al.* 1967; Kleinfeld *et al.* 1973; Rubino *et al.* 1976: cosmetic grade talc: Miller *et al.* 1971; Nam and Gracey, 1972);
 - the risks associated with occupational exposures were higher when fibrous forms of magnesium silicate minerals (talc as well as asbestos) were present (*e.g.*, Kleinfeld *et al.* 1963; Kleinfeld *et al.* 1964; Pott and Friedrichs, 1972; Blejer and Arlon, 1973; Pott *et al.* 1974; Wagner *et al.* 1975; Stanton *et al.* 1981), being linked to fibrotic diseases of the lungs, such as talcosis and pneumoconiosis (*e.g.*, Dreesen and Dalla Valle, 1935; Porro and Levine 1946; Greenburg, 1947; Kleinfeld *et al.* 1973); and
 - exposure to cosmetic grade talcum powders themselves were associated with adverse tissue responses and adverse human health effects, including deaths in some cases (*e.g.*, Molnar *et al.* 1962; Blumel *et al.* 1962; Jenkins, 1963; Hughes and Kalmer, 1966; Migaki and Garner, 1969; Moss, 1969; Miller *et al.* 1971; Nam and Gracey, 1972; Wagner *et al.* 1975; Brouillette and Weber, 1978; Mofenson *et al.* 1981; Cramer *et al.* 1982; Kaiser *et al.* 1982; Pelling and Evans, 1986; Kupryjanczyk, 1989; Buz'Zard and Lau, 2007; Shukla *et al.* 2009; Shim *et al.* 2015).

Also relevant to this discussion of what was known based on review of studies published in the scientific literature is the fact that Johnson & Johnson itself published a review article in 1976 (Hildick-Smith, 1976). In that paper, Dr. Hildick-Smith provided a summary of the scientific literature from the 1940's to the 1970's, listing many studies that provide proof that talc has toxic properties at certain doses and by different routes of exposure, *i.e.*, talc itself is a toxic compound.

41. Considered together, there is a large body of reliable scientific information, of all types (studies in cells, tissues, animals and humans), that identifies talcum powder products as posing a hazard to human health. The types of toxicity produced are dependent on the route of exposure and the purity of the talc product. Yet, there is no controversy concerning the existence of a hazard and a need to control exposures to talc dusts and powders. Exposure to talc body powders internally (direct tissue contact) can cause a variety of adverse effects that are related to the known irritant and inflammatory properties of talc itself as well as the presence of other chemical components that exist in cosmetic grade talcum powder products. It is important to note as well that in 2007, the Canadian government took action to require warning on talc product labeling for cosmetics that warned of the dangers of inhaling talc particles. Then, in 2018, Canadian regulators performed a new risk assessment for talc and published its findings in both draft (December 2018) and final (April 2021) form. As described in those documents, Canadian authorities in two agencies, Environment and Climate Change Canada and Health Canada, found that talc exposure posed a risk to human health, leading Canada to initiate actions to amend the talc listing on its cosmetic ingredient Hotlist as it relates to perineal use of talc body powders.⁴² The amendments to the Hotlist for talc are still ongoing as of the date of this report.

V. Talcum Powder Products: Perineal Application and Internal Exposure

42. The human health concern with talcum powder products in the current case is ovarian cancer in women who applied the products repeatedly to the perineal area. The first step to consider in the process of producing ovarian cancer with perineal talc dusting is exposure. Although dermal exposure is also a potential route of concern, the absorption of talc particles across skin has been assumed to not be of consequence when assessing toxicity of talcum powder products unless the skin has been damaged in some way. Instead, exposure assessments of talc applied dermally have focused on entry into the body through portals such as the lungs, the vagina or the mouth (IARC, 1987; EPA, 1992; IARC, 2010). The toxicity potential of talc has been shown to be affected by the route of exposure, with more significant toxicity linked to penetration of small talc particles into tissues and triggering of cytotoxic responses at the local site of tissue interactions (EPA, 1992). Therefore, consistent with existing data, talc would be less toxic following oral

⁴²<https://www.canada.ca/en/environment-climate-change/services/evaluating-existing-substances/risk-management-approach-talc.html>

exposure where the interaction with stomach acids, and presence of the gastrointestinal barrier, would affect the expected toxicity potential.

43. When assessing the potential for human exposure to talc applied to the perineal area, the focus has been on entry into the body through the vagina. There also is evidence that application of talcum powder products results in inhalation exposure of talc dusts (e.g., the September 2017 study by Longo and colleagues entitled “*Below the Waist Application of Johnson & Johnson Baby Powder*”; Jasuja *et al.* 2017; Frank and Jorge, 2011; van Huisstede *et al.* 2010; Wells *et al.* 1979). An early study by the National Institute of Occupational Safety and Health (NIOSH) in 1972 showed that talcum powder products samples available commercially contained fibers and that exposure to fibers would occur during diapering (JNJ000231304-318); this study was received by Johnson and Johnson at least by March of 1974. Based on its chemical nature, talc delivered as a powder in consumer products can be inhaled while being applied (EPA, 1992; IARC, 2010). Regardless of the portal of entry, lungs versus the vagina, talc-induced local tissue toxicity would be expected to be produced in tissues that are accessed following perineal dusting with talc. With respect to inhalation exposure of talcum powder products and the potential for inhaled particles to migrate to the ovaries, studies have shown that asbestos fibers can move from the lung to other body organs via the lymphatic system (Suzuki and Kohyama, 1991; Bunderson-Schelvan *et al.* 2011). The lymphatic system is known to be involved in the transport of inhaled particles from the lung to distant sites (Leak, 1980; Stuart, 1984; Adamson and Prieditis, 1998; JNJ000046293). Thus, it is biologically plausible that talc particles that embed or deposit within lung tissue could be transported away from the lungs through the lymphatic system in the same way that other particles, and even asbestos, have been shown to travel to sites distant from their portal of entry, the lungs. With respect to genital dusting of talcum powder products, I considered the available evidence related to the ability of talc to migrate from the site of application, *i.e.*, perineal or vaginal application, to the ovaries. When considering that evidence, it is important to note that there are often misconceptions about female anatomy with respect to the vagina as an entry point for chemicals and particles. In fact, it is important to consider the following discussion of the anatomy of the female reproductive tract (Alexander *et al.* 2004):

“A common misperception is that the vagina is a straight tube pointing upward to the sacral promontory. Most illustrations (in both patient and clinician educational materials)

are inaccurate and perpetuate this image. They give the impression that items placed in the vagina could easily fall out...Radiographic colpography (18, 19) has shown that the vagina is normally a curved organ with two distinct portions: a lower convex portion and a wider upper portion that lies in an almost horizontal plane when the woman is standing. The angle between the upper and lower axes is 130 degrees”.

44. The migration of talc internally after perineal application was discussed by scientific and regulatory bodies that reviewed the toxicokinetics of talc (EPA, 1992; IARC, 2010) as well as by FDA in a recent letter (P-47). As FDA concluded in 2014, “...***the potential for particulates to migrate from the perineum and vagina to the peritoneal cavity is indisputable. It is, therefore, plausible that perineal talc (and other particulate) that reaches the endometrial cavity, Fallopian Tubes, ovaries and peritoneum may elicit a foreign body type reaction and inflammatory response that, in some exposed women, may progress to epithelial cancers.***” [***emphasis added***]. A review of the scientific literature revealed that FDA’s conclusion is supported by a variety of studies that include, but are not limited to, studies examining or reviewing the migration of particles in humans (*i.e.*, Egli and Newton, 1961; de Boer, 1972; Parmley and Woodruff, 1974; Venter and Iturrulde, 1979; Blumenkrantz *et al.* 1980; Gardner *et al.* 1981; Iturralde and Venter, 1981; Halme *et al.* 1984; McCalley *et al.* 1985; Wright *et al.* 1996; Kunz *et al.* 1996; Heller *et al.* 1996; Kunz *et al.* 1997; Kadanali *et al.* 2001; Kunz and Leydendecker, 2002; Kissler *et al.* 2004; Sjosten *et al.* 2004; Kunz *et al.* 2007; Zervomanolakis *et al.* 2007; McDonald *et al.* 2019a; McDonald *et al.* 2019b; Johnson *et al.* 2020). Additionally, authors have described the potential for abdominal exposure to talc particles following perineal application of talcum powder products in women (Longo and Young, 1979); the abdominal cavity in humans is reached directly through migration of particles from the vagina, through the reproductive tract and up towards the ovaries, which are suspended within the peritoneal space. These studies are important because they demonstrate that inert particles routinely move from the lower female reproductive tract (vagina) up into fallopian tubes and towards the ovaries. There also are data demonstrating the presence of talc particles in the ovaries of women who had reported use of talcum powder products on the genital area (*e.g.*, Heller *et al.* 1996; Cramer *et al.* 2007), as well as animal studies showing that in some species talc can migrate from the lower to the upper genital tract (*e.g.*, Phillips *et al.* 1978; Gardner *et al.* 1981; Henderson *et al.* 1986; Edelstam *et al.* 1997).

Given the differences between animals and humans in terms of anatomy of the genital tract, the studies in humans are the most reliable in terms of human health risk assessment and the toxicokinetics of talc applied externally to the perineal area. The weight-of-the-evidence shows that inert particles routinely move from the lower female reproductive tract (vagina) up into the uterus, the fallopian tubes and towards the ovaries. Therefore, in terms of the potential for exposure following perineal application of talc body powders, the available data support statements by the FDA that particulates can move from the vagina up the reproductive tract in women to provide for exposure to internal organs, including the ovaries.

45. An early study examining the issue of migration of substances through the female reproductive tract was undertaken to better understand the time relationships and precise mechanisms of transport of inert particles or spermatozoa in humans (Egli and Newton, 1961). The study was designed to determine whether, under reasonably controlled conditions, carbon particles could be transported quickly from the vagina to the fallopian tubes. Three women who were scheduled for hysterectomy voluntarily participated and were administered carbon particles under anesthesia after being positioned on their backs. Three to four milliliters of sterile carbon particles in a Dextran suspension were deposited in the upper portion of the vagina. Oxytocin was administered intra-muscularly at that time as well. Immediately after injection, the fallopian tubes were removed and examined for the presence of carbon particles; a very short time was allowed for potential transport. In two of the three women, carbon particles were recovered from the fallopian tubes 28 and 34 minutes after injection into the vagina. The authors concluded: *“These data, together with other work in animals and humans, support the belief that the motility of spermatozoa is not the chief factor in sperm transport. Contractions of the muscle of the uterus or other reproductive organs may be very important, and it is possible that oxytocin may play a part in this process.”*[emphasis added] A similar study was performed a decade later (DeBoer, 1972) where the author reported on the movement of carbon material up the genital tract in a series of patients undergoing abdominal surgical procedures. The women were injected (some cervical instillations and some uterine instillations) with a colloidal carbon suspension (India ink), and in some cases women also were given an injection of oxytocin. Surgeries were performed at various times after injection, from 15 minutes to 24 hours after injection. The authors stated *“...there was no doubt that the inert carbon material was frequently and rapidly transported from the*

uterus to the tubes in both phases of the menstrual cycle.” [emphasis added] Passage of particles from the vagina to the uterus was observed in two of 37 patients examined, while particles were detected in the fallopian tubes in 30% of patients with cervical instillation and in 50% of patients with uterine instillation. Two years later, the migration of environmental substances externally in women was discussed in connection with the origins of ovarian mesotheliomas (Parmley and Woodruff, 1974). In the discussion section the authors stated: “*The uniqueness of the female peritoneal cavity is that environmental substances may more easily reach it by passage through the vagina and Fallopian tubes (Fig. 13). Conversely, no such entry is available in the male...*” [emphasis added] All three of these studies provided early notice of the ability of particles to move up the female reproductive tract.

46. In addition to studies in humans, experiments were conducted in different animal species to examine the ability of talc to be distributed beyond the site of exposure, oral or intra-vaginal application (Phillips *et al.* 1978). As discussed by the authors, their studies were prompted by the safety concerns raised in the scientific literature with respect to talc, specifically they indicate that “*the possibility of a causal relationship between particular types of tumours and the presence of talc has caused disquiet about its safety-in-use*”. With respect to the issue of movement of talc within the reproductive tract, rabbits were administered either a single intra-vaginal dose (50 mg total talc in 0.5 ml volume; three rabbits tested) or six daily doses of the same amount of talc (also 3 rabbits). In all cases, the animals were sacrificed 72 hours after the dosing ceased. The urogenital tracts were dissected to determine if radioactivity could be detected. After one dose of radiolabeled talc, radioactivity was detected only in the vagina. In the rabbits administered multiple doses of radiolabeled talc, radioactivity was detected at the site of application but also in the cervix, the uterus and the fallopian tubes, but not the ovaries. Thus, migration or translocation occurred in the rabbit reproductive tract to a limited extent, although not all the way to the ovaries. Even though studies in animals are not ideal in terms of modeling the female reproductive tract, this study again provided notice of the ability of particles to move within the reproductive tract.

47. In another human study in 1979, scientists reported use of a radionuclide procedure designed to evaluate the migration of a particulate radioactive tracer from the vagina to the peritoneal cavity and ovaries, as well as the determination of the patency of the pathways between

these two extremes of the female reproductive system (Venter and Iturralde, 1979). The procedure employed radiolabeled human albumin microspheres that were deposited into the vaginas of 24 patients one day before they were to undergo a gynecological surgery. Sequential images were obtained during the 24-hour period, and after the surgeries were completed radioactivity levels in the removed organs and tissues were counted with a scintillation detector. The authors reported that in 14 out of 21 cases it was possible to measure radioactivity levels in the adnexa (*i.e.*, fallopian tubes, ovaries) separately from the uterus. Nine patients showed marked radioactivity in the tubes and ovaries, while in five patients the radioactivity levels were not much higher than the background. In all five of these patients with background levels of radioactivity detected, the authors reported that severe tubal occlusion was confirmed. As the authors discussed: ***“Evidence is available for migration of different substances in either direction within the female reproductive system between the peritoneal cavity and ovaries via the tubes, uterus and vagina, and the outside. Various living organisms actively follow this pathway in both directions. Gases, fluids, dyes and contrast media can easily be introduced from the vagina into the peritoneal cavity. If transit can take place so easily, it is probably the same for many chemical substances used for hygienic, cosmetic or medicinal purposes, many of which may have potential carcinogenic or irritating properties.”*** [emphasis added] This paper provided evidence that migration of talc upwards into the female reproductive tract was considered more than a possibility at this point in time.

48. In a similar study reported in 1985 (McCalley *et al.* 1985), scientists performed a prospective study to evaluate the efficacy of radionuclide hysterosalpingography (RNHSG) using a technique with some modification that had been described by Venter and Iturralde (1979). The authors state: ***“As these investigators demonstrated, technetium labeled human albumin microspheres will normally migrate spontaneously from the vagina to the ovaries.”*** [emphasis added] This new study confirmed the findings of the 1979 study and showed that if the fallopian tubes are not patent, migration cannot continue. Most importantly, the authors provided the following conclusions: ***“Our work confirms the observation of Iturralde and Venter that inert particles are easily and spontaneously transported from the vagina through the genital tract to the ovaries. This implies that sperm motility, although possibly essential, e.g., for penetration of the ovum, may not be the basic factor in sperm transport. It also confirms that pathogenic materials***

deposited in the vagina can be transported onto the ovary and may play a role in the etiology of some ovarian carcinomas. [emphasis added] The scientific studies providing notice on the ability of particles to migrate continued to build.

49. Another source of human data related to migration of substances upwards in the female reproductive tract is found in a book chapter that was prepared from a presentation made at the 7th International Symposium on Controlled release of Bioactive Materials (July 27-30, 1980) (Gardner *et al.* 1981). The chapter provides an overview of what was known at the time regarding movement of particles and other materials up the female reproductive tract from the vagina. The chapter was focused on using that route of exposure as a method for delivery of drugs in women. The author stated: “*The concept of a particulate drug-delivery system is further supported by studies in humans, which **demonstrate the movement of inert particles through the reproductive tract.** Following placement in either the vagina, cervix, or uterus, particles such as carmine or carbon black have been observed to **migrate into the fallopian tubes or peritoneal cavity.**”* [emphasis added] Additionally, the authors described new studies in Stumptail monkeys. They reported that vaginally delivered drug particles were able to migrate through the cervix into the uterus. They stated: “*Transcervical migration from the vagina to the uterus (24 hours post-insertion) was observed to some degree in six out of eleven animals. In these studies, it appeared that capsule diameters less than 300 microns in diameter showed preferential migration. However, one animal out of three at the largest capsule diameter did show migration of greater than three percent of the inserted microcapsules.*” In a study in one baboon, the authors reported that six hours after insertion of two different sizes of tracer microcapsules there was essentially no difference in transcervical migration between the two sizes, and that migration was rapid (within six hours) into the cervix, uterus, and fallopian tubes. These studies provided additional evidence for migration of substances from the vagina upwards into the reproductive tract, including a study in primates.

50. Three additional animal studies appeared in the scientific literature in 1985 and 1986 that are relevant to the issue of talc migration in the female reproductive tract (Wehner *et al.* 1985; Henderson *et al.* 1986; Wehner *et al.* 1986). Henderson and colleagues from the Tenovus Institute reported on the ability of talc to migrate from the vagina to the ovary in rats (Henderson

et al. 1986); this same research group had published data on the finding of talc in the human ovary (Henderson *et al.* 1971; Henderson *et al.* 1979). The authors stated: “**Direct communication between the external environment and the peritoneal cavity exists in the female via her genital tract.**” [*emphasis added*] The study was undertaken after Henderson and colleagues (1984) showed that injection of talc beneath the bursal sac around the ovary in rats was accompanied by “associated epithelial changes not inconsistent with the histological picture of premalignancy.” In the first of this new set of experiments by Henderson and colleagues in 1986, eight rats received intra-uterine talc (100 mg/ml suspension; 250 µl volume) injections. Rats in Group I (four rats) were sacrificed five days after talc exposure, and their ovaries were removed. Rats in Group II (four rats) received further talc uterine injections six days or 15 days after initial treatment. On day 20, two rats were sacrificed, and the remaining two rats were sacrificed 22 or 30 days after initial treatment. In all cases, ovaries were removed and analyzed for the presence of talc particles. In a second experiment employing vaginal delivery of talc, twelve rats were divided into two groups of six. Rats in Group I had a 250 µl suspension of talc (100 mg/ml) deposited into their vagina, while rats in Group II received vehicle treatment. Two animals in each group were sacrificed 24 hours, 48 hours and four days after treatment. Their ovaries were removed and processed for detection of talc particles. Particles of talc were identified in the ovaries of all rats at all time points where talc had been instilled into the uterus. With vaginal instillation, talc particles were detected in two of the animals when sacrificed after four days.

51. In the two studies published in 1985 and 1986, Wehner and colleagues (Wehner *et al.* 1985; Wehner *et al.* 1986) investigated the translocation of talc in animals. As noted in the studies, these were commissioned and funded by PCPC.⁴³ At the time these studies were conducted, Dr. Wehner was also a consultant with Johnson & Johnson. Wehner *et al.* (1985) first examined the ability of bone black particles to translocate from the vagina upwards into the oviducts in monkeys. Five monkeys were instilled with 0.3 ml of a 4% bone black suspension in the posterior fornix during their mid-menstrual cycle, followed by injection of oxytocin intramuscularly. Animals were sacrificed either one hour (n=3) or 72 hours (n=2) after vaginal instillation was performed. The authors stated that they did not believe any translocation had occurred but could not rule it out with certainty. Thus, two additional monkeys were administered

⁴³ The PCPC was known at the time as the CTFA (see footnote on page 329 of Wehner *et al.* (1986)).

radiolabeled talc in a pilot study (single doses of talc) and the animals were sacrificed after 72 hours. Again, the authors reported no translocation occurred in the animals. In a follow-up study, Wehner *et al.* (1986) again examined talc migration in monkeys. Unlike the monkey studies of Gardner *et al.* (1981) and the studies in rats and rabbits discussed above, this was the only animal study published up to this time where the authors reported no translocation of talc to the oviducts. Six monkeys were used by Wehner and colleagues in this *in vivo* study where low doses of radiolabeled talc (125 mg) were instilled into the vagina of the monkeys under sedation, 30 times over 45 days. In three of six monkeys tested, there was no talc found and the investigators believed it may have been due to menstrual flow that had occurred in the monkeys at different times during the experiment. The authors also stated that their results differed from those of an earlier group (Gardner *et al.* 1981) and suggested the differences may have been due to use of much lower doses of talc, different materials, and longer sedation times. The data by this group were inconsistent with other animal data but most importantly they were inconsistent with the human data which is the most relevant data in terms of the issue of movement of particles in women.

52. By the 1990's the issue of migration of substances upwards in the female reproductive tract was discussed in the medical literature in review articles, indicative of the general acceptance in the scientific community of the ability of particles to migrate up the female reproductive tract. In a 1994 review, Lauchlan (1994) states that talc can reach the ovaries through a patent vagina and describes the action of genital application of talc powder as a mode for internal exposure to talc particles. In another review (Wright *et al.* 1996), the authors began by stating: "*Dusting powders are used...**These powders can gain access to the abdominal cavity through the vagina** and during surgery, and they have caused numerous complications that have serious, life-threatening consequences.*" [**emphasis added**] In the discussion section of this paper the authors pointed out that the known toxicity of talc in human tissue and "*the ability of the female genital tract to transport particles to the abdominal cavity*" should lead to physicians discouraging their patients to use talcum powder in the perineal area or when dusting diaphragms.

53. In a 1996 article, scientists directly addressed the issue of perineal talc usage and ovarian talc particle burden (Heller *et al.* 1996). The scientists examined ovarian tissue from 24 women undergoing ovary removal; the patients were interviewed regarding talc usage. Twelve

women reported frequent perineal talc applications, while twelve reported no use, although diapering history was not available in all women (the authors considered baby powder use during diapering as a potential source of talc powder exposure in the past). The authors conclusions were stated in their abstract as follows: *“The detection of talc in all ovaries demonstrates that it can reach the upper genital tract. Widespread exposure to talc during diapering may contribute to the ubiquitous presence of talc in ovarian tissue.”* This paper has been criticized based on the issue of potential laboratory contamination that could have contributed to the results, as well as the fact that women reporting no perineal use had talc detected in ovarian tissue. Regardless of these limitations, however, the results showing higher overall particles counts in women reporting perineal application of talc are nevertheless consistent with the ability of talc particles to migrate up the female reproductive tract. More importantly, this study is but a small piece of the overall evidence that supports the ability of talc to migrate from the vagina to the ovaries.

54. In a series of studies conducted in the 1990’s and into the 2000’s, Dr. Kunz reported on the importance of the uterine peristaltic pump to the ability of sperm to be rapidly transported through the female reproductive tract (Kunz *et al.* 1996; Kunz *et al.* 1997; Kunz and Leyendecker, 2002; Kunz *et al.* 2007). In the initial studies, Kunz and colleagues (Kunz *et al.* 1996) used hysterosalpingoscintigraphy as a tool to examine transport of particles up the reproductive tract in women. Technetium-labelled albumin spheres from 5 to 40 microns (a size similar to talc particles found in body powders) were instilled at the posterior vaginal fornix (upper vaginal area) and the path of the spheres was followed. The authors reported immediate movement of the spheres up the tract, with spheres detected in the fallopian tubes within minutes. The movement was greatest during the follicular phase of a woman’s cycle. The authors stated: *“Furthermore, our studies with inert particles suggest that this directed ascension is not a property of the spermatozoa and is thus not provided by mechanisms such as chemotaxis, but rather constitutes a specific utero-tubal function controlled by the dominant follicle in that the uterine myometrium with its specific architecture (Goerttler, 1930) is activated and contracts in a manner providing this directed transport.”* [emphasis added] In other words, the motility of the sperm was not needed for transport to occur. In a 2007 study (Kunz *et al.* 2007), Dr. Kunz used methods similar to ones employed in his 1996 study. He again showed that technetium-labelled albumin spheres from 5 to 40 microns (a size similar to talc particles found in body powders) that had been instilled into the

vagina were transported up the female genital tract, both with and without oxytocin use. The paper describes the now well-established ability of small particles to migrate upwards, with greatest movement occurring during the follicular phase of a woman's cycle (see reviews of the role of the uterine peristaltic pump, *e.g.*, Kunz *et al.* 1997; Kunz and Leyendecker, 2002; Zervomanolakis *et al.* 2007).

55. Several additional studies were identified in the scientific literature that related to particle migration in women (Kadanali *et al.* 2001; Sjosten *et al.* 2004; McDonald *et al.* 2019a; McDonald *et al.* 2019b; Johnson *et al.* 2020). Kadanali and colleagues (2001) discussed upwards transport in the genital tract in women. Although the focus of their paper was on movement of sperm in women with IUD devices in place, one group of women were treated by intra-vaginal instillation of albumin microspheres (referencing use of the method of Iturralde and Venter) instead of sperm. The microspheres were from 10 to 90 microns in size (also in the size range of talc particles found in body powders). The authors reported that while active sperm migration was greatly inhibited (9 of 14 subjects, 65%) in the presence of an IUD, passive transport of the particles was not affected (10 of 10 subjects, 100%) in IUD-bearing women. These data provided additional support for the migration of particles upwards into the fallopian tubes of women, even women with an IUD device implanted. With respect to powder migration specifically, Sjösten and colleagues (2004) reported results of a study in humans to confirm migration that had been observed in an animal model. In the study, one group of women (n=12) underwent a gynecological exam with powdered gloves the day before an abdominal hysterectomy and another group was examined with powdered gloves four days before surgery (n=12). Two control groups were examined with powder-free gloves (n=12 or n=14). Cell smears were taken from the peritoneal fluid and during the operation further smears were taken from the fallopian tubes, uterine cavity and cervical canal. The authors reported that retrograde migration of starch particles had occurred in humans after examination with powdered gloves. The authors concluded: "*Consequently, powder or any other potentially harmful substance that can migrate from the vagina should be avoided.*" Of the more recent studies, the studies by McDonald and colleagues (2019a, 2019b) addressed the issue of migration of talc in women with ovarian cancer that reported perineal use of talc body powders. The studies aimed to differentiate the presence of talc in pelvic lymph nodes due to talc exposure versus contamination. Considered together these studies showed that talc

particle burden in nodes correlated with perineal usage of talc powder. These studies provide additional support for the ability of talc to translocate from the genital area of women up the reproductive tract. The most recent study (Johnson *et al.* 2020) was discussed by Health Canada in its 2021 talc risk assessment (Health Canada, 2021). The regulators stated with respect to this study:

“Some further work was done (Johnson et al. 2020) to compare talc particles from commercially available powders to those found in pelvic tissues taken from 11 randomly selected ovarian cancer patients with a known history of long-term perineal talc use. PLM and SEM/EDX were employed to measure the talc particles, and extensive measures were taken to control for contamination. The talc particles taken from tissues of the patients were most often located within benign tissue, reactive fibroblastic tissue, or chronically inflamed tissue near a tumour, rather than within tumours; the presumption is that talc accumulates in benign tissue some time prior to the tumour developing. The particle size and dimensions of talc particles found in the commercial samples are consistent with those found in the pelvic tissues of the patients: 77.7% of commercial samples and 83.5% of talc from tissues fall within the same ranges for aspect ratio and area. This lends support to the idea that externally-applied talc can migrate from the perineal area.”⁴⁴

56. Considered together, these studies conducted in both humans (*in vivo* and *ex vivo* studies) and in animals demonstrate the ability of particles to be transported upwards against gravity in the female reproductive tract. These studies provide support for the FDA statement in 2014 that the potential for particulates to migrate from the perineum and vagina to the peritoneal cavity “*is indisputable*”, and for Health Canada’s conclusions in 2021 that genital talc use poses a potential health risk to humans that will be addressed with new risk mitigation actions.⁴⁵ More importantly, studies going as far back as the 1960’s provided direct evidence for the potential of particles to migrate from the vagina to the ovaries in humans. At least in 2004, Imerys was acknowledging that “*compelling evidence*” for migration had been published (IMERYS288328-330).

⁴⁴ See pages 21-22 of the Canadian 2021 Talc Screening Assessment.

⁴⁵ <https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75453a-eng.php>

57. Before leaving this discussion of talc migration, it is important to point out that in its review of the issue of talc migration in the genital tract of women, the CIR panel mentions many of the same studies described above; however, there is no mention of eight additional human studies and reviews of the issue (*i.e.*, Parmley and Woodruff, 1974; McCalley *et al.* 1985; Lauchlan, 1994; Wright *et al.* 1996; Kunz *et al.* 1996; Kunz *et al.* 1997, Kadanali *et al.* 2001; Kunz and Leyendecker, 2002; Kunz *et al.* 2007). All eight of these papers were available by the time of the CIR review. Therefore, it appears the CIR panel failed to account for all the studies that informed on the issue of migration of particles, such as talc moving upwards through the reproductive tract. This omission is particularly important given the fact that the CIR panel stated the following with respect to the epidemiological studies and how that data was considered:

“The Panel stated that causation would depend on the migration of talc from the perineum to the ovaries. There is no conclusive explanation for the presence of talc in the ovaries reported in some studies. However, the Panel agreed that there is no known physiological mechanism by which talc can plausibly migrate from the perineum to the ovaries.” [see page 23 of the CIR Final Report dated April 12, 2013]

The CIR process (discussed in detail below) was limited by the omission of a series of human studies and scientific review papers directly relevant to the issue of talc particle migration. Based on the totality of the scientific evidence, which includes more than the data available to or even considered by the CIR panel in 2013, I agree with the FDA’s conclusions on this issue and assign little weight to the conclusions reached by the CIR panel concerning talc migration. As already discussed above, in the recent talc risk assessment performed by Health Canada with respect to perineal exposure to talc in cosmetic body powders, they concluded that *“there is the potential for perineal exposure to talc from the use of various self-care products”*⁴⁶, a finding consistent with the FDA.

VI. Talc and Cancer

58. In this case, the toxicity of concern for talcum powder products exposure in humans is cancer. The specific risk issue for this case is exposure to powdered talc products through perineal or genital application, as well as inhalation exposure, leading to migration of talc internally, resulting in ovarian cancer. The issue of talc and cancer risk in humans has been

⁴⁶ See page 43 of the Screening Assessment document

recognized for decades (see papers discussed in reviews such as EPA, 1992; IARC, 2010; IARC, 2012). Although ovarian cancer is the focus of the current case, other forms of cancer have also been linked to talc exposure (*i.e.*, lung cancer with inhalation exposure to talc; IARC, 2010). To determine whether there is a reasonable basis to conclude there may be a health hazard associated with talcum powder products, it is important to review the totality of the evidence to determine whether there is scientific support. Therefore, I have considered available *in vitro* and *in vivo* toxicology data, mechanistic data, epidemiological studies, and other evidence. In reviewing the evidence, I employed the methodology as discussed earlier in my report (*e.g.*, paragraphs 11, 12, and 13).

59. There is a body of mechanistic data that also needs to be considered when looking at the issue of talcum powder products and risks to human health. It is important to remember that administration of even a single dose of talc in animals has been shown to produce adverse effects locally, at the site of exposure, that have included granulomatous reactions, cellular proliferation, and adhesions (as reviewed by EPA, 1992). Thus, evidence shows that talc exposure induces local tissue responses that are adverse effects, not simple adaptive effects, and those effects lead to tissue damage.

60. Talc can induce toxicity in tissues and cells through direct contact. The studies discussed above related to the ability of talc to migrate from the vagina upwards in the reproductive tract in women are important evidence that talc can arrive at sites where local tissue toxicity would be produced, such as the fallopian tubes and the ovaries. Studies looking at local tissue effects of talc would be important when examining a mechanistic basis for talc carcinogenicity in humans. Starting in the 1980's, studies appeared in the scientific literature related to understanding the local tissue effects of talc. In an early study, the cytotoxicity of seven different respirable talc products (expected to be of high purity) provided to researchers by the PCPC were studied (Davies *et al.* 1983). Specifically, the fibrogenic potential of talc was investigated through use of a cell bioassay (macrophage toxicity) using murine peritoneal macrophages. All seven talc samples tested were found to be cytotoxic and the authors stated they "*would be expected to be fibrogenic in vivo*". In another study (Hamilton *et al.* 1984), direct exposure to what was claimed to be asbestos-free talc (via single intra-bursal injection) on the surface of the ovaries of rats was associated with adverse

effects including “*focal areas of papillary change*” on the surface epithelium of the ovaries, often discussed as pre-neoplastic lesions; thus, talc was toxic to ovarian tissue in mammals. Beck and colleagues (1987) examined the local tissue toxicity of talc dust (stated to be asbestos-free and granite-free dust), as well as other mineral dusts,⁴⁷ *in vivo* in animals (hamsters) following a single intra-tracheal instillation of a dust into lung tissue. The experiments examined the dose-response relationship (0.15, 0.75 and 3.75 mg talc/100 g body weight) and the time course (1 to 14 days post-exposure) of the effects of dust exposure in lung tissue. The authors stated: “*One day after exposure, both talc and granite dust resulted in elevated enzyme levels and pulmonary cell numbers in BAL [bronchial alveolar lavage fluid]. Macrophage phagocytosis was also inhibited. Based on results from earlier studies, response levels were either intermediate between nontoxic iron oxide and toxic α -quartz or comparable with n -quartz. The response to granite dust diminished fairly rapidly over time. By contrast, after talc exposure, there was a more persistent elevation in enzyme levels, and macrophage phagocytosis remained depressed. These results indicate that when a similar mass was deposited in the lungs, **talc caused more lung injury than did granite.**” [emphasis added]* In another study (Radic *et al.* 1988), talc was shown to suppress immune system function in rats injected subcutaneously with talc. Talc induced granulomatous reactions in the animals, and spleen cells from talc-treated rats suppressed the immune response. Each of these studies provided evidence that talc is toxic to cells and tissues that are contacted with talc dusts/particles, including ovarian tissue.

61. In 1993, the results of chronic GLP-quality studies conducted from 1984-1986 in rats and mice were reported (NTP, 1993; P-0832 was the draft report). In these studies, using standard study methods of the time, the potential for talc (stated to be asbestos-free) to produce cancer following inhalation was studied. The study rationale was stated as follows: “*Talc was nominated by NIOSH in 1978 for testing by NTP because of the paucity of adequate information on its carcinogenicity and because of widespread human exposure. The inhalation route was chosen because it is the most common route for human exposure.*” Although earlier studies had investigated the cancer potential of talc (see review in IARC, 1987), limitations in study design affected their utility for human health risk assessment (*i.e.*, less than lifetime exposures, small group sizes, *etc.*). An important feature of this study was the interim sacrifices performed in both

⁴⁷ Granite dust was tested in this study as well.

rats and mice in all three exposure groups of both sexes (see Table 5 and Table 11 of NTP, 1993). This meant that the evolution of lung lesions was examined in the animals, allowing for identification of a potential mechanism for lesions that developed in lung tissue. The study authors concluded:

“Under the conditions of these inhalation studies, there was some evidence of carcinogenic activity of talc in male F344/N rats based on an increased incidence of benign or malignant pheochromocytomas of the adrenal gland. There was clear evidence of carcinogenic activity of talc in female F344/N rats based on increased incidences of alveolar bronchiolar adenomas and carcinomas of the lung and benign or malignant pheochromocytomas of the adrenal gland.”

This information alone is significant for human health risk assessment; however, the findings from the interim sacrifices in both rats and mice were extremely useful in terms of identifying a mechanism for lung tumors in rats and mice. The text from the study is quoted below as it provides important support for a mechanism for talc-induced carcinogenesis.

“Although the inflammatory response was basically similar in rats and mice, there were important species differences. The lesions in rats were generally more extensive and more severe than those in mice at similar exposure concentrations. In rats, foreign body giant cells were occasionally observed and some of the alveolar macrophages developed the morphological characteristics of epithelioid macrophages. More importantly, the inflammatory lesions in rats were accompanied by interstitial fibrosis, hyperplasia of alveolar type II epithelial cells, and, infrequently, squamous metaplasia of the alveolar epithelium.” [emphasis added; see page 51 of NTP 1993]

*“A **potential mechanism** for the development of pulmonary neoplasms associated with insoluble particulate substances is that **the prolonged stimulus for cell replication, due not only to cell injury but to the release of mitogenic growth factors from alveolar macrophages, provides a favorable environment for the promotion and progression of spontaneously initiated cells.** The interim evaluations in the NTP talc study clearly demonstrate **a progressive impairment of homeostatic growth regulation in the areas of chronic inflammation and fibrosis associated with talc deposition in rats.** Hyperplasia of the alveolar epithelium was evident at 6 months and became more extensive and severe*

with duration of exposure. Not only were there increased numbers of cells (hyperplasia), but some cells assumed morphologic features atypical of regenerating or differentiated type II cells (epithelial dysplasia). The altered or dysplastic epithelium was particularly evident in areas of fibrosis. The squamous metaplasia observed in female rats also represents altered differentiation of populations of alveolar epithelial cells and is notable in light of the development of squamous cysts and squamous cell carcinomas.” [emphasis added; see pages 54-55 of NTP, 1993]

Thus, these data from interim sacrifices in rats and mice provided an important signal for human safety. The 1993 NTP study has been criticized and conclusions reached by the original authors have been questioned (*i.e.*, Carr, 1995; CIR, 2013). Yet, even with its limitations, the study provides important information on talc toxicity that is relevant to assessing the risks of cancer in humans. In fact, scientists that initially reviewed the study supported the use of the data for listing of talc in NTP’s Report on Carcinogens (RoC; discussed in more detail below). It also should be noted that based on an inhalation route of exposure in rats and mice that was employed in the studies (NTP, 1993), the studies would not be expected to produce ovarian tumors in rats or mice given the route of exposure that would severely limit any perineal exposure to talc. Moreover, unlike humans, the ovaries of rats and mice are completely covered by a bursal sac, making direct access to ovarian tissue unlikely when exposure is assumed to be due to vaginal penetration and migration to the ovaries.

62. In more recent studies, the biologic basis of effects in cells and tissues associated with exposure to talc that could be linked to carcinogenesis were evaluated. In one study, (Buz’Zard and Lau, 2007) normal ovarian cells in culture were treated with increasing concentrations of talc in solution, either with or without the presence of a chemotherapeutic agent that has been shown to have anti-cancer activity (*i.e.*, inhibits oxidative damage in cells, induces apoptosis of cancer cells). The authors reported that talc treatment increased generation of reactive oxygen species in ovarian cells and induced neoplastic transformation. In another study looking at cellular changes associated with mineral exposure, Shukla and colleagues (2009) examined mineral pathogenicity of four different particles, including asbestos and non-fibrous talc. Human lung mesothelial cells and human ovarian epithelial cells in culture were employed. Both types of cells were exposed to increasing concentrations of asbestos, talc, titanium oxide and glass beads.

The asbestos was identified as crocidolite asbestos with a mean size of 7.4 μm and had greater than 3:1 length to width ratio. The talc was stated to have a mean size of 1.1 μm and was stated to occur as *“platy particles that were uniform in appearance”* (by field emission scanning electron microscopy). The results of most interest in terms of mechanism of action that relates to the potential to produce a carcinogenic response in tissue included the cell viability data and the changes in gene expression induced by exposure to asbestos and talc. As expected, asbestos fibers were toxic to human cells, both lung and ovarian cells; asbestos is a known human carcinogen. The authors reported that the lung cells were more sensitive to the toxic effects of asbestos; however, testing of only two doses of asbestos limit the conclusions that can be drawn about differences between cells. In the case of talc, lung cell viability was decreased in a dose-dependent manner; decreased viability was reported at talc doses of 15 and 20 $\mu\text{g}/\text{m}^2$. When two lower doses of talc, 1 and 5 $\mu\text{g}/\text{m}^2$, were tested in ovarian cells, there was no effect on cell viability. Gene expression changes in lung mesothelial cells also were examined, and exposure to asbestos for up to 24 hours was associated with significant effects on gene expression. The authors reported that fewer gene expression changes occurred in ovarian cells exposed to asbestos. They also reported that fewer gene expression changes were observed in lung cells following exposure to talc at a dose of less than 5 $\mu\text{g}/\text{m}^2$ for up to 8 hours, and no significant changes in ovarian cell gene expression were observed with talc exposure. However, when the list of genes whose expression was affected by asbestos and talc was examined, it is seen that some of the genes affected are involved in cellular processes that relate to oxidative stress and inflammation. The authors of this study failed to test talc with the same rigor that asbestos was tested in their study, limiting the data collected on talc itself. Nevertheless, the study did reveal statistically significant increases in *ATF3* and *IL8* expression by asbestos and non-fibrous talc at certain concentrations. The data collected with asbestos exposure supports known toxicity of induction of oxidative stress as a mechanism underlying carcinogenesis (IARC, 2012). In a more recent study examining the biologic basis of effects in cells and tissues associated with exposure to talc that could be linked to carcinogenesis, Mandarino and colleagues (2020) focused on the effect of talc exposure on immunosurveillance and the activity of macrophages in a high estrogen environment; in addition to the release of tissue-damaging factors from macrophages, these cells could have compromised immunosurveillance activity that results in decreased tumoricidal activity. The authors stated:

“We found that murine ovarian surface epithelial cells (MOSEC), a prototype of certain forms of ovarian cancer, were present in larger numbers after co-culture with macrophages treated to a combination of talc and estradiol than to either agent alone or vehicle. Control particles (titanium dioxide, concentrated urban air particulates or diesel exhaust particles) did not have this effect. Co-exposure of macrophages to talc and estradiol has led to increased production of reactive oxygen species and changes in expression of macrophage genes pertinent in cancer development and immunosurveillance. These findings suggest that in vitro exposure to talc, particularly in a high-estrogen environment, may compromise immunosurveillance functions of macrophages and prompt further studies to elucidate this mechanism.”

63. The same research group (Hillegass *et al.* 2010) further examined the pathogenicity of asbestos as compared to other particles, including talc. The authors reported that their analysis of microarray data confirmed that lung cells were *“more responsive than ovarian cells to crocidolite asbestos or non-fibrous talc, and that crocidolite asbestos elicited greater responses in both cell types when compared to non-fibrous talc”*. As before, however, the group failed to test talc across a range of doses that would be necessary to examine its effects in these assays, using only doses that were equivalent to asbestos even though it was known that the crocidolite asbestos would be expected to be more potent in terms of biological reactivity than talc. The authors did, however, report that *“the pathogenesis of asbestos-associated diseases is most commonly associated with a persistent inflammatory response initiated by ROS, growth factors, and/ or various pro-inflammatory factors such as cytokines or chemokines”*. Therefore, this paper provided further evidence supporting the mechanism of inflammation and generation of reactive oxygen species as important to the tissue responses induced with exposure to particles that would include both asbestos and talc.

64. In a more recent study (Shim *et al.* 2015), the effect of talc to induce oxidative stress *in vivo* following administration of talc was examined. Rats were exposed to talc via whole-body inhalation at concentrations of 0, 5, 50 and 100 mg/m³, six hours per day, five days per week, for four weeks. It should be remembered that in a GLP-quality lifetime study in rodents (NTP, 1993), rats were exposed to talc via whole-body inhalation at doses of 0, 6 and 18 mg/m³, six hours

per day, five days per week, and there was clear evidence of talc-induced chronic inflammation, reparative processes and cellular proliferation (as evidenced by lung pathological changes observed at interim sacrifices of 6, 11, and 18 months). This shorter-term study in rats by Shim *et al.* (2015) focused on understanding the role of oxidative stress in the tissue responses to talc, a general mechanism that has been linked to chronic inflammation and cancer, including ovarian cancer (*e.g.*, Saed *et al.* 2017; Saed *et al.* 2018; Fernandes *et al.* 2015; Landskron *et al.* 2014; Kamp *et al.* 2011; Grivennikov *et al.* 2010; Lu *et al.* 2006; Rakoff-Nahoum, 2006; Senthil *et al.* 2004; Ness *et al.* 2000; Savant *et al.* 2018; Ding *et al.* 2021). Shim and colleagues (2015) reported that inhalation of talc for four weeks was associated with macrophage aggregation and oxidative damage in the lung, including significantly increased expression of superoxide dismutase 2 (SOD 2), a biological indicator of oxidative damage.

65. In several references authored by the same research group, the effects of talc exposure to induce oxidative stress in ovarian cancer cells have been investigated and described (Fletcher *et al.* 2018; Fletcher and Saed, 2018; Fletcher *et al.* 2019). The first reference describes a presentation at a scientific meeting in March of 2018; the researchers reported on the ability of talc to affect markers of oxidative stress in ovarian cancer cells in culture (Fletcher *et al.* 2018). Both normal ovarian epithelial cells and cancerous ovarian epithelial cells were incubated with talc at concentrations of 0, 200 and 500 µg/ml for 24, 48 and 72 hours. The talc was purchased from Sigma Aldrich.⁴⁸ There was a marked increase in mRNA levels of pro-oxidant enzymes in both ovarian cell lines as compared to controls (untreated), and a marked decrease in mRNA levels of anti-oxidant enzymes in both cell lines as compared to controls (untreated cells). These changes, indicative of a pro-oxidant state in the cells (oxidative stress), were reported to occur as early as 24 hours after exposure. The authors concluded: *"This is the first report to show that talcum powder induces biological effect by further enhancing the redox state in both normal ovarian epithelial cells as well as ovarian cancer cells. The results of this study will provide a molecular basis to previous reports that link genital use of talcum powder to increased risk of epithelial ovarian cancer."* In the second presentation in 2018 by this same laboratory (Fletcher and Saed, 2018), additional investigation of the effects of talcum powder on ovarian cancer cells was discussed. The objective of the studies performed was to determine the effects of talcum powder

⁴⁸ The Sigma Aldrich website indicates that the talc sold is pharmaceutical grade talc.

on levels of the cancer antigen, CA-125, in both normal ovarian cells and ovarian cancer cells. The authors stated that levels of CA-125 are elevated in more than 80% of women with advanced ovarian cancer and 50% of women with early-stage cancers. Ovarian cells were exposed to 0 or 1000 µg/ml talc for 72 hours and levels of CA-125 were determined by ELISA methods. The authors reported that there were increases in CA-125 levels in response to talc treatment in both normal and cancerous cells. The authors concluded: *“Talcum powder induces a biological effect by further enhancing CA-125 levels in ovarian cancer cells as well as in normal ovarian epithelial cells. This will provide a molecular basis to previous reports that link genital use of talcum powder to increased risk of epithelial cancer.”* The 2019 publication with the same authors (Fletcher *et al.* 2019) is a peer-reviewed paper describing the 2018 studies⁴⁹ related to the effects of talc on the expression of key redox enzymes, CA-125 levels, and cell proliferation and apoptosis in normal and ovarian cancer cells. The authors stated: *“These findings are the first to confirm the cellular effect of talc and provide a molecular mechanism to previous reports linking genital use to increased ovarian cancer risk.”* In a review of the pathogenesis of ovarian cancer by Dr. Saed and colleagues (Saed *et al.* 2018), the importance of oxidative stress to pathogenesis and prognosis of ovarian cancer is discussed. Thus, the effects of talc in cells and tissues that are linked to oxidative stress provide additional insight into the molecular basis of talc-induced ovarian cancer in humans.

66. Talc body powders manufactured and sold by Imerys and Johnson & Johnson were a mixture of compounds, many of which have toxic properties. There is consistent evidence linking talc as well as the other components of talc with initiation of inflammation at the local site of exposure (discussed above), as well as evidence that talc induces biologic effects that result in pre-cancerous lesions (NTP, 1993). Inflammation is a well-studied mechanism of carcinogenesis (*e.g.*, Fernandes *et al.* 2015; Grivvennikov *et al.* 2010; Fleming *et al.* 2006; Lu *et al.* 2006; Rakoff-Nahoum, S. 2006; Ness and Cottreau, 1999). As discussed in a recent review of the topic of inflammation and cancer (Grivvennikov *et al.* 2010), there are several basic facts about inflammation and cancer that include the following: (1) chronic inflammation increases cancer risk; (2) subclinical, often undetectable inflammation may be as important in increasing cancer risk; (3) various types of immune and inflammatory cells are frequently present within tumors; (4)

⁴⁹ It is common for scientists to first publish their findings in the form of an abstract or presentation for a scientific meeting and then follow with a full paper that is published in the peer-reviewed literature.

immune cells affect malignant cells through production of cytokines, chemokines, growth factors, prostaglandins, and reactive oxygen and nitrogen species; (5) inflammation impacts every single step of tumorigenesis, from initiation through tumor promotion, all the way to metastatic progression; (6) in developing tumors anti-tumorigenic and pro-tumorigenic immune and inflammatory mechanisms coexist, but if the tumor is not rejected, the pro-tumorigenic effect dominates; (7) signaling pathways that mediate the pro-tumorigenic effects of inflammation are often subject to a feed-forward loop; and (8) certain immune and inflammatory components may be dispensable during one stage of tumorigenesis but absolutely critical in another stage. Therefore, in the case of talc, even if tissue samples from ovarian tumors fail to exhibit signs of active chronic inflammation, an inflammatory role for talc is not ruled out. Instead, the role of talc in inducing the tumorigenic response could be linked to earlier stages of cancer progression.

67. With respect to inflammation and ovarian cancer specifically, a recent prospective epidemiological study performed by investigators at the National Institutes of Health has linked specific pro-inflammatory markers in blood with the presence of ovarian cancer in women (Trabert *et al.* 2014); the authors suggest that these pro-inflammatory mechanisms may be linked to the increased risk of ovarian cancer seen in women exposed to compounds such as talc and asbestos. Other supporting evidence for a link of inflammation with carcinogenesis following talc exposure in women are the studies that have shown that talc exposure can induce oxidative stress in cells (discussed above). Therefore, there are multiple plausible mechanisms that may be related to the cancer hazard posed by perineal talc body powder exposure in women. Additionally, the fact that talc can act as a cancer promoter is also relevant (Stenback *et al.* 1986). Finally, it is important to note that the link of talc with inflammatory processes is an underlying toxic insult that can lead to cancer. This mechanism is consistent with mechanisms linked to other particles that induce cancer (*i.e.*, asbestos and silica; Moller *et al.* 2010, Moller *et al.* 2013; IARC, 1987; IARC, 2010; IARC, 2012). It is also important to realize that there is latency associated with cancer pathogenesis which would also apply in the case of talc.

68. When considered together, the scientific literature on the biological effects of talc, as well as asbestos and other constituents routinely found in talc (discussed above), provide sufficient evidence to show that these chemicals produce cellular changes that have been linked to

carcinogenesis and that the biological mechanism for carcinogenesis (ovarian and/or lung) following exposure to talcum powder products likely involves induction of a chronic inflammatory response. A review of the IARC monographs for talcum powder product constituents, such as asbestiform talc and non-asbestiform talc, nickel, cobalt, and chromium, reveals similarities in the biological effects that are discussed as underlying the carcinogenic potential of the individual compounds. Moreover, available evidence indicates that local exposure to talc particles is likely involved, where “local exposure” means exposure at or near the site of injury, in this case exposure of the ovary and ovarian cancer. It is important to realize as well that in the case of almost any human drug used to treat a disease or symptoms of some condition, the exact molecular mechanism by which the drug produces its effects also are not known. Thus, not knowing every detail about the molecular mechanism underlying talcum powder products and carcinogenesis does not mean that the available data fail to provide support for a likely mechanism. In fact, we know some important things about talc, information that supports the biologic plausibility of the relationship between talc exposure and human cancer. This mechanistic data provides highly plausible biological support for the signal for human cancer risk identified from the epidemiological (discussed below) and animal data.

69. When considered together with general principles of toxicology, the available data relating to mechanism of carcinogenicity of talcum powder products, where the body powders are a mixture of compounds with carcinogenic hazard, indicate that the various compounds in talcum powder products would be expected to produce at least an additive effect on the risk of cancer based on their ability to induce similar biological responses that underly carcinogenesis (Eaton, D.L. and S.G. Gilbert. 2013. Principles of toxicology. In: *Casarett & Doull's Toxicology: The Basic Science of Poisons, 8th edition*. Klaassen, C.D. (ed.). McGraw-Hill: New York: NY. Chapter 2, pp. 19-20; EPA, 2000). The likely mechanism for cancer is related to the similar cellular events that have been linked to carcinogenesis in the case of the known components of talcum powder products.

70. It is well-established that there are two types of chemical carcinogens: genotoxic and non-genotoxic (Klaunig, 2013). A genotoxic carcinogen is one that is mutagenic, may be a complete carcinogen, produces tumors that exhibit a dose-response relationship with exposure,

and for which there is no threshold for cancer initiation⁵⁰. A non-genotoxic carcinogen is one that is not a direct mutagen, exhibits a threshold for tumor development, produces tumors that exhibit a dose-response relationship with exposure, may only function as a tumor promoter, does not directly damage DNA, and may exhibit species, strain and tissue specificity in response. The available evidence indicates that talc may be a non-genotoxic carcinogen, as defined here, based on the evidence showing that it is not genotoxic (in most assays), requires repeated dosing of sufficient duration for tumors to be produced, has been shown to exhibit activity as a tumor promoter for known carcinogens (*i.e.*, benzo(a)pyrene; Stenback *et al.* 1986), exhibits species and tissue specificity in tumor responses (associated with local site of exposure), and has not been shown to directly damage DNA. The available animal cancer data has not been assessed for a threshold for tumor development, but the NTP study data did indicate that the tumor response was a high dose effect. Human studies, however, have indicated that ovarian cancer exhibits a dose-response in terms of being associated with an increased duration of use and frequency of use of talc-based products (*e.g.*, Cramer *et al.* 1999; Terry *et al.* 2013; Wu *et al.* 2015; Schildkraut *et al.* 2016; Berge *et al.* 2018; Penninkilampi and Eslick 2018). Therefore, the available evidence indicates that talc's plausible mechanism of action to induce cancer would be through non-genotoxic (indirect) pathways.

71. I also would like to point out that talc powder is used clinically to cause an acute inflammatory response in a procedure known as pleurodesis. This procedure is designed to cause the two layers of the lung pleura, parietal and visceral layers, to stick together so that the space between the layers is filled with scar tissue. Typically, only a few ounces of fluid would be found between the parietal and visceral pleural membranes, but the fluid can build up to as much as a few liters and is known as a pleural effusion. Both mechanical and chemical means are used to initiate the lung scarring that is needed to treat these effusions. In the case of chemical pleurodesis, a substance such as talc powder can be placed into the chest cavity near the lungs to produce an acute inflammatory response that leads to scarring. The size of the talc particles used in the procedure are important; severe inflammatory effects were more likely when a talc powder with smaller particles, about 50% less than 10 μm , was employed (Arellano-Orden *et al.* 2013). It is

⁵⁰ Asbestos has been identified as a genotoxic carcinogen.
(https://www.atsdr.cdc.gov/csem/asbestos/how_does_asbestos_induce_pathogenic_changes.html).

important to note that typical talcum powder products, including those manufactured and sold by Imerys and Johnson & Johnson, contain mostly small particles, less than 10 μm (Zazenski *et al.* 1995; JNJ000326966; IMERYS095244; IMERYS120564-565). Thus, the pleurodesis literature provide further support for inflammation as a known tissue response to talc, even though the type of inflammatory response produced in pleurodesis procedures is acute, not a chronic response as is characteristic of carcinogenesis.

72. As discussed above in paragraph 33, an increased human cancer risk has been linked to components of talcum powder products, such as asbestos. By the 1930's, evidence was available linking asbestos exposure with lung disease, including lung cancer; by the mid 1950's, the majority of scientists believed that asbestos could cause lung cancer, and likely other forms of cancer, in humans (Doll, 1955); and by the 1960's, evidence had accumulated linking asbestos exposure with ovarian cancer, with some studies reporting an increased incidence in women exposed to asbestos. Beginning in the 1970's, the issue of ovarian cancer in women began to be discussed with respect to talcum powder product exposure (Henderson *et al.* 1971; Henderson *et al.* 1979). Since that time, the study of, evidence for, and discussion of, a cause and effect relationship between talc exposure and human ovarian cancer risk has continued to develop in light of the totality of the data (*e.g.*, Cramer *et al.* 1982; Hartge *et al.* 1983; Natow, 1986; Whittemore *et al.* 1988; Booth *et al.* 1989; Harlow and Weiss, 1989; Harlow *et al.* 1992; Chen *et al.* 1992; Rosenblatt *et al.* 1992; Tzonou *et al.* 1993; Cramer and Xu, 1995; Purdie *et al.* 1995; Shushan *et al.* 1996; Chang and Risch, 1997; Cook *et al.* 1997; Green *et al.* 1997; Daly and O'Brans, 1998; Eltabbakh *et al.* 1998; Godard *et al.* 1998; Cramer, 1999; Wong *et al.* 1999; Ness *et al.* 2000; Langseth and Kjaerheim, 2004; Mills *et al.* 2004; Jordan *et al.* 2007; Merritt *et al.* 2008; Wu *et al.* 2009; Rosenblatt *et al.* 2011; Kurta *et al.* 2012; Terry *et al.* 2013; Houghton *et al.* 2014; Wu *et al.* 2015; Schildkraut *et al.* 2016; Berge *et al.* 2018; Penninkilampi and Eslick, 2018; Taher *et al.* 2020; O'Brien *et al.* 2020; Davis *et al.* 2021; Woolen *et al.* 2022; Phung *et al.* 2022; O'Brien *et al.* 2024). A review of these studies as a whole shows that exposure to talc by routine genital application is reported to increase the risk of ovarian cancer in women by about 30% (*e.g.*, Cramer *et al.* 1982; Whittemore *et al.* 1988; Booth *et al.* 1989; Harlow and Weiss, 1989; Harlow *et al.* 1992; Rosenblatt *et al.* 1992; Purdie *et al.* 1995; Shushan *et al.* 1996; Chang and Risch, 1997; Cook *et al.* 1997; Cramer *et al.* 1999; Gertig *et al.* 2000; Ness *et al.* 2000; Mills *et al.* 2004; Merritt

et al. 2008; Wu *et al.* 2009; Rosenblatt *et al.* 2011; Kurta *et al.* 2012; Terry *et al.* 2013; Schildkraut *et al.* 2016; Berge *et al.* 2018; Penninkilampi and Eslick, 2018; Davis *et al.* 2021; Woolen *et al.* 2022; O'Brien *et al.* 2024). Not all studies identified in the published scientific literature have reported a statistically significant increased risk of ovarian cancer following talc exposure in women (e.g., Hartge *et al.*, 1983; Chen *et al.* 1992; Tzonou *et al.* 1993; Godard *et al.* 1998; Wong *et al.* 1999; Langseth and Kjaerheim, 2004; Houghton *et al.* 2014; O'Brien *et al.* 2020). With such a large group of epidemiological studies, with varying designs, sizes of the populations studied, and varying measures of exposure, it is not surprising that there are studies that show both an increase in risk as well as those that failed to report such results. Yet, in the large group of studies (more than 25 studies) reporting statistically significant findings, the increased risk is consistently seen to be in the range of 30%. Even in the studies that reported non-statistically significant findings, there often was a trend towards an increased risk in women who used talcum powder products. As recent as 2020, statistically significant findings regarding the association between genital use of talc powder and risk of ovarian cancer were published after analysis of pooled data results from four cohort studies. The paper included a subgroup analysis of the data that focused on women with patent reproductive tracts (O'Brien *et al.* 2020). In response to comments made to Dr. O'Brien regarding her findings she responds as follows:

"We completely agree with Dr. Harlow and colleagues that our results, particularly the analyses limited to women with intact reproductive tracts, should not be discounted because of a lack of statistical significance. For all estimates, we reported 95% CIs so readers could consider size and precision. The qualifier that there was no statistically significant association between ever genital powder use and ovarian cancer is a factual report of a test of the null hypothesis; we never equated the lack of statistical significance to evidence of no association.

We conducted subgroup analyses with an a priori hypothesis that intact reproductive tracts are required to be susceptible to the exposure. Therefore, even though we stated that findings from subgroup analyses should be interpreted as exploratory, we do not consider them all equally important and agree that the positive association among women with patent reproductive tracts (HR 1.13; 95% CI 1.10-1.26) is consistent with the hypothesis that there is an association between genital powder use and ovarian cancer."

In their most recent work, O'Brien and colleagues (2024) have reported results of an assessment of recall bias in the prospective cohort study known as the "Sister Study" and found that *"although results show how differential recall would upwardly bias estimates, corrected results support a positive association between use of intimate care products, including genital talc, and ovarian cancer."* In a recent meta-analysis and systematic review of eleven different studies (Woolen *et al.* 2022), the authors reported a statistically significant increased risk of ovarian cancer associated with frequent perineal powder use by women (31% to 65% increased risk). Based on the totality of the data, which includes human epidemiological data related to talcum powder product use and cancer risk in women that is considered in conjunction with the biological data on talc migration, as well as cellular and animal data regarding inflammation and talc's induction of carcinogenicity, the weight-of-the-evidence supports the conclusion that use of talcum powder products may pose a health hazard to women.

73. As a part of my risk assessment, I also considered whether there is a dose response. In the current case where the chemical of concern is a particle, and the route of exposure of concern is external application of a powder that then migrates internally, and the powder itself is a mixture of a variety of compounds some of which are known human carcinogens, the concept of dose is more complex. The human studies do not provide a measure of a single dose in terms that are typical of the cellular (*in vitro*) or animal studies, *i.e.*, mg talc per kg body weight, or mg talc per m³ inhaled air, or mg talc per ml of solution. In the case of the talc database, dose for human is expressed terms of frequency and duration of exposure. It is a general principle of pharmacology and toxicology that just as the likelihood of a response increases with dose, the likelihood of a response increases with longer term use, and more frequent use (Eaton and Gilbert, 2013). The available *in vitro* and animal study data show that there is a dose-response relationship for talc toxicity (*e.g.*, EPA, 1992; NTP, 1993; IARC, 2010; Buz'Zard and Lau, 2007; Shukla *et al.* 2009; Shim *et al.* 2015). The animal cancer data, when considered in conjunction with the cellular data, indicate that talc is a carcinogen and there likely is a dose-response threshold for tumor development in rodents (NTP, 1993). There are several human studies that provide evidence of a

dose-response relationship⁵¹ for talc exposure and ovarian cancer in women (e.g., Cramer *et al.* 1999; Terry *et al.* 2013; Schildkraut *et al.* 2016; Cramer *et al.* 2016; Berge *et al.* 2018; Penninkilampi and Eslick, 2018; Woolen *et al.* 2022; O'Brien *et al.* 2024). Therefore, there are sufficient scientific data supporting the existence of a dose-response relationship for genital talc use and an increased risk of ovarian cancer.

74. In 1978, the U.S. Congress amended Section 301(b)(4) of the Public Health Service Act, to require the Secretary of the Department of Health and Human Services (DHHS) to publish an annual report that contains a list of all substances that “*are known to be human carcinogens or may reasonably be anticipated to be human carcinogens and to which a significant number of persons residing in the United States are exposed*”.⁵² The process of producing the list, known as the Report on Carcinogens, or RoC, results from periodic meetings and is a process managed by the NTP on behalf of DHHS. There have been 15 RoC processes to date, the 15th RoC being published in 2021.⁵³ Talc was considered as part of the 10th and 12th RoC processes. The 10th RoC meeting where talc was discussed was held in 2000, while the 12th RoC meeting on talc was held in 2005. The 10th RoC deferred action to list talc as a carcinogen, citing a need for additional information; the 12th RoC also deferred action to list talc. It is important to note that the NTP RoC nominated talc for consideration for listing in the 10th RoC based on a review of the available data by a body of scientists without input from industry, and without any direct interaction with other industry groups or representatives with a conflict of interest, consistent with the procedures set forth by IARC (IARC, 2006). Johnson & Johnson, Imerys, and PCPC influenced the 10th RoC process as I discuss later in paragraph 96. It is also important to note that a review of the minutes of the 10th RoC indicates that even though the only public comments made to the panel were from industry representatives, many of the reviewers supported listing non-asbestiform talc as reasonably anticipated to be a human carcinogen (IMERYS 039060 through 085).

⁵¹ Given the nature of talc as particles and fibers that cannot be metabolized in the body and remain in tissues where they deposit, duration and frequency of exposure are appropriate surrogates for assessing the dose-response relationship between talc use and an increased risk of cancer in human epidemiological studies.

⁵² <https://ntp.niehs.nih.gov/pubhealth/roc/history/index.htm>

⁵³ <https://ntp.niehs.nih.gov/whatwestudy/assessments/cancer/roc>

75. In 2010, the International Agency for Research on Cancer (IARC) Working Group published its assessment of the carcinogenic potential of non-asbestiform talc. The review of talc had occurred in 2006 and included only those papers available up to 2006. In its 2012 statements about cancer and fibers of the type that are known to occur in talc (IARC, 2012), IARC pointed out that conclusions about asbestos and carcinogenic risk applied to six types of fibers, including “*talc containing asbestiform fibres*” (see page 219 in IARC, 2012). It is important to note here that the IARC review process is not open for public comment and all conclusions reflect the consensus decisions made by global experts in their field and without influence from industry. Additionally, this review occurred after the NTP talc reviews had been completed. Unlike the NTP RoC reviews, the IARC panel was able to reach a consensus regarding the cancer risks posed by talc. The IARC panel concluded that perineal use of non-asbestiform talcum powder products was “*possibly carcinogenic to humans*” (a Group 2B classification) and inhalation of non-asbestiform talc was “*not classifiable as to its carcinogenicity*” (a Group 3 classification). This finding provided additional evidence for the weight-of-the evidence assessment I performed. It should be noted that the 2006 IARC panel did not have access to studies performed after 2006 which include but are not limited to Langseth *et al.* (2008), Terry *et al.* (2013), Wu *et al.* (2009 and 2015), Schildkraut *et al.* (2016), Cramer *et al.* (2016), Berge *et al.* (2018), Penninkilampi and Eslick (2018), Taher *et al.* 2019, O’Brien *et al.* (2020), Health Canada (2021), Davis *et al.* 2021; Phung *et al.* (2022); Woolen *et al.* (2022), and O’Brien *et al.* (2024).⁵⁴ These additional studies and/or analyses provide further evidence of the link of talc exposure in women and an increased risk of ovarian cancer. Langseth *et al.* (2008) points to the need for additional study of the relationship between talc use and ovarian cancer as the studies available as of 2008 indicated that use of cosmetic talc in the perineal area may be associated with ovarian cancer risk. Terry *et al.* (2013) performed one of the largest meta-analyses with the talc database. The authors reported that genital use of talcum powder products significantly increased the risk of all types of ovarian cancer. The paper by Schildkraut *et al.* (2016) provided support for the existence of a dose-response relationship between talc use and increased risk of ovarian cancer in women. The papers by Wu and colleagues (2009 and 2015) describe population-based case-control studies of the relationship of ovarian cancer risk to exposures that included use of talc; in both papers the authors reported a statistically significant association between talc use and ovarian cancer. Schildkraut and colleagues

⁵⁴ See also paragraph 72.

(2016) reported results from a case-control study where there was a statistically significant increase in risk of epithelial ovarian cancer linked to use of talc body powders, including genital talc use, with duration and frequency of use being important. Cramer *et al.* (2016) reported results from a retrospective case-control study of talc use and the risk of ovarian cancer; the authors reported there was a statistically significant increased risk of ovarian cancer with talc use and the trend increased with longer-term use. Berge *et al.* (2018) reported a statistically significant increased risk of serous carcinoma of the ovary, as well as the identification of a dose-response relationship (increased duration of use). Penninkilampi and Eslick (2018) performed another meta-analysis of the studies in women exposed to talc through perineal dusting with talc body powders and reported that “*there is a consistent association between perineal talc use and ovarian cancer*”. Taher *et al.* (2019) reviewed the available scientific literature studies on the epidemiology of talc and ovarian cancer risk and concluded that perineal talc use is a possible cause of ovarian cancer. O’Brien *et al.* (2020) performed a pooled analysis of available prospective cohort studies and found that in the subgroup of women who reported ever use of talc powder in the genital area and had a patent reproductive tract, there was a statistically significant increased risk of ovarian cancer. Health Canada’s talc screening assessment was reported in final form in April of 2021; it was stated in the report that: “*With regards to perineal exposure, analyses of the available human studies in the peer-reviewed literature indicate a consistent and statistically significant positive association between perineal exposure to talc and ovarian cancer. The available data are indicative of a causal effect.*” Davis *et al.* (2021) was a pooled analysis including the largest number of African American cancer cases. The authors reported a statistically significant increased risk of ovarian cancer in women (African American and White) that had used talc-based body powders. The recent meta-analysis by Woolen and colleagues (2022) also included a large number of ovarian cancer cases and focused on frequent (at least two times per week) perineal use of talc body powders and ovarian cancer; they reported a statistically significant increased risk of ovarian cancer in women that were frequent users of talc products. Additionally, Phung and colleagues (2022) evaluated the effect of genital talcum powder use in women with and without endometriosis and reported that the risk of ovarian cancer was increased in women that reported genital use of talc-based body powder. They also reported that the risk of ovarian cancer was higher in women with endometriosis who applied talcum body powder to their genitals. Finally, as already mentioned above, O’Brien and colleagues’ analysis of recall bias in the prospective cohort study known as the Sister Study

(O'Brien *et al.* 2024) also found that results “support a positive association between use of intimate care products, including genital talc, and ovarian cancer.” These additional studies and evaluations add to the weight of evidence that genital use of talcum powder products may be a health hazard.

76. Therefore, the weight-of-the-evidence indicates that genital exposure to talcum powder products increases the risk of ovarian cancer in women. This conclusion is supported by data that includes, but is not limited to the following: (1) the known toxic effects of talc and the other components of talcum powder products; (2) studies that have identified the biologically plausible mechanisms for cancer in humans; (3) the likelihood that talc particles can reach the ovaries; (4) the existence of a dose-response relationship for toxicity including the risk of cancer; and (5) the large human database that includes studies conducted over a period of 40 years showing a consistent signal for ovarian cancer in women exposed to talcum powder products.

VII. The Role of Industry in Talcum Powder Product Safety Assessments

77. In support of my opinions, I have reviewed and considered thousands of documents related to the actions of Johnson & Johnson, Imerys, and PCPC with respect to talc and human health risks and safety assessment. The documents related to Johnson & Johnson date back into the 1950's and 1960's (*e.g.*, patents filed by the company; studies published by company employees; internal company documents). Documents related to Johnson & Johnson and the PCPC date back to the 1970's (*e.g.*, internal company documents; exhibits to depositions of company employees or corporate representatives). Documents related to Imerys and the PCPC date back to the 1990's (*e.g.*, internal company documents; exhibits to depositions of company employees or corporate representatives). The evidence shows that the defendants worked both individually and collaboratively to present a uniform position to regulators, the scientific and medical community, and consumers, that talcum powder product use did not present a risk of ovarian cancer in humans.

78. Evidence supporting Johnson & Johnson's early efforts to influence the safety information disseminated publicly about talc in the late 1970's involved the 1975 U.S. Pharmacopeia (USP) listing for talc. Based on their efforts, the USP listing was changed in 1980 to omit the warnings “Do not apply to open wounds” and “Do not inhale” (JNJ000343613;

JNJNL61_000030770; JNJ000343580; JNJ000343612; JNJ000343614; JNJ000343946; JNJ000343611; trial testimony of Dr. John Hopkins dated February 8, 2018). Johnson & Johnson relied on their assertion that there was no asbestos present in talc that met the USP standards, even though evidence shows they were aware of the presence of some level of asbestos in their products at that time (as discussed above). Moreover, by the 1970's Johnson & Johnson was aware that some scientists believed that exposure standards for asbestos should be applied to fibrous talc (JNJ000231422-428). Evidence suggests that industry knew or should have known about the significant human health risks posed by exposure to cosmetic talc body powders well before 1975. Therefore, the evidence suggest that Johnson & Johnson failed to provide accurate information to the USP regarding the issue of the presence of asbestos in talc. Moreover, in asserting that "*normal exposure to cosmetic talc presents no inhalation hazard*" (JNJNL61_000030770), the company was making statements that were not scientifically defensible given the knowledge available by 1975 concerning talc and the hazards of inhalation exposure (as discussed above). Therefore, it is my opinion that Johnson & Johnson knew or should have known that use of cosmetic talc body powders had been reported to lead to lung injury when the talc was inhaled, and to lead to adverse tissue reactions when internal tissues were exposed to talcum powder products.

79. Also, in the 1970's, documents show that Johnson & Johnson made efforts to influence the science around the issue of asbestos in talc and the link of talc with ovarian cancer (P-0055; P-0344; P-0002). The efforts included a discussion with the FDA Commissioner in 1974 where Johnson & Johnson stated: "*Our very preliminary calculation indicates that substantial asbestos can be allowed safely in a baby powder.*" (P-0660). Later in the same document Johnson & Johnson states that "*if the results of any scientific studies show any questions of safety talc, Johnson & Johnson will not hesitate to take it off the market*" (P-0660). Given the fact that Johnson & Johnson was aware, or should have been aware, of the science that had accumulated by that time linking asbestos exposure with both ovarian cancer and lung cancer, the position by the company regarding the presence of any asbestos in talc body powders is inconsistent with protecting public health when the issue involved exposure to a cosmetic product, one without any benefit. Importantly, consumers were not informed of the safety concerns regarding the presence of asbestos in talcum powder products.

80. In discussing the issues related to industry and its actions to influence the public perception of talc safety, it is important to understand the role of the CIR in cosmetic ingredient safety assessments. As already mentioned above, the CIR process is industry-funded and is administered independent of the FDA. While FDA may consider CIR conclusions, the FDA does not adopt their findings (PCPC_MDL00096145, PCPC_MDL00044971, Deposition of Dr. Linda Loretz). The panel's role is to review the available safety information for the ingredient and to come to a consensus about its safety. The CIR reports are open for public comment before they are finalized. Over the years, the CIR has reviewed and reported on over 5,000⁵⁵ ingredients, yet only 12 have been found to be "*unsafe*" for use.⁵⁶ The current CIR meetings involve no more than two days of discussion for ingredients and ingredient groups (talc was one ingredient amongst a multitude of ingredients in 17 ingredient groups) during which time the panel reviews the data and comes to its conclusions regarding ingredient safety (deposition testimony of Dr. Linda Loretz October 1 and 2, 2018). None of the CIR expert panel members personally review the relevant published studies; instead, the members review only the report drafted by CIR staff (transcript of the testimony of Dr. Andersen at pages 3157-3158, *Echeverria v. Johnson & Johnson*). This is a much more abbreviated review process than is employed by IARC when it is making a cancer hazard assessment.⁵⁷ For example, in the IARC reviews, the Working Group, drafts the consensus document as a group while working together for seven to eight days (MDL_KELLY00002701-2702). Care is taken to ensure that detailed summaries of studies are written by relevant experts, unlike the CIR reports which are written by employees of the PCPC instead of the experts on the panel. Also, unlike the IARC review process, where panel members chosen for a review are ones with specific expertise in the scientific issues that are addressed for a chemical (IARC, 2006), the CIR panel typically includes less specialized scientists; and the make up of the panel changes little from meeting to meeting even though the issues raised for individual ingredients could be very different (deposition testimony of Dr. Linda Loretz in 2018). Therefore, from a scientific perspective, the IARC process involves a much more detailed scientific evaluation of the issues surrounding a cancer hazard than the issues addressed by any CIR review.

⁵⁵ Testimony of CIR Director from 1993 to 2013, Dr. Alan Andersen dated 8/10/2017 (*Echeverria v. Johnson & Johnson*).

⁵⁶ <https://www.cir-safety.org/cir-findings>

⁵⁷ See description of the process at: <http://monographs.iarc.fr/ENG/Preamble/currentbscientificintro0706.php>

81. In deposition testimony over several days in 2018⁵⁸, corporate representatives of the PCPC provided detailed descriptions of the CIR process. The testimony of the former Director of the CIR (Dr. Andersen in *Echeverria v. Johnson & Johnson* dated 8/10/2018) also provided details about the CIR process, including the talc process, and the close relationship with industry. Additional information can be found in internal company documents as well (e.g., P-0561; P-0595). The lack of independence of the CIR process from PCPC operations and influence by industry is apparent after review of these sources, even though a different impression is given through the CIR website. For example, at the CIR website the following is stated:

“The Cosmetic Ingredient Review was established in 1976 by the industry trade association (then the Cosmetic, Toiletry, and Fragrance Association, now the Personal Care Products Council), with the support of the U.S. Food and Drug Administration and the Consumer Federation of America. Although funded by the Council, CIR and the review process are independent from the Council and the cosmetics industry.”

As will be discussed below with respect to the talc CIR review, the process was not independent of industry, did not include physicians with expertise in gynecological cancer or female pelvic anatomy, and involved a truncated discussion among the panel members as compared to the IARC assessment process.

82. The CIR has set forth procedures for its safety assessments (CIR 2018; IMERYS 118788). As discussed in the CIR procedures document, the purpose of the CIR is to “*determine those cosmetic ingredients for which there is a reasonable certainty in the judgement of competent scientists that the ingredient is safe under its conditions of use*”. The same document defines “safety” or “safe” to mean that there is “***no evidence in the available information that demonstrates or suggests reasonable grounds to suspect a hazard to the public under the conditions of use that are now current or that might reasonably be expected in the future***” [*emphasis added*]. Based on this definition of “safe” and the purpose stated by the CIR, this means that the standard applied to a CIR review, and that should guide the outcome of that review, is whether there is evidence that demonstrates or suggests a hazard. If there is any such evidence

⁵⁸ Dr. Linda Loretz of the PCPC was deposed as a corporate representative of the PCPC on 17 July 2018, 1 October 2018, and 2 October 2018. Mr. Mark Pollack was deposed as a corporate representative of the PCPC on 28 July 2018.

of a hazard under conditions of use, then the standard would not be met, and the ingredient should not be deemed safe for use in cosmetics.

83. In the case of talc, a final version of the CIR panel report was published in 2013 (CIR, 2013) and then appeared in the published literature in 2015 (Fiume *et al.* 2015). The CIR panel stated that talc is “*safe in the present practices of use and concentration in cosmetic products*” (CIR, 2013). There was no CIR report published on talc before 2013 even though there was evidence for concern about the safety of talcum powder products that had been voiced within the scientific community for decades and that reliable evidence had been published in peer-reviewed journals even before the CIR came into being in 1978 (as discussed above). Based solely on the CIR standard for safety, existing evidence provided a reasonable basis for finding that the perineal use of talcum powder products increases the risk of ovarian cancer. Moreover, as discussed above with respect to the issue of talc migration, I described how that assessment was incomplete and resulted in conclusions that are not supported by available science.

84. Important evidence in support of my opinions comes from admissions contained in documents and testimony by the trade organization known in the past as the CTFA, and since 2007 known as the PCPC. Publicly available documents show that PCPC has been intimately involved with talc safety issues over the period from the early 1970’s up to today (see deposition testimony of Dr. Linda Loretz, page 700). Together with Johnson & Johnson and Imerys, PCPC coordinated and presented a position to regulators and the medical community that talc was safe. This position was presented regardless of significant evidence to the contrary.

85. In their deposition testimony in 2016 and 2018, Mr. Mark Pollak and Dr. Linda Loretz, the designated PCPC corporate representatives, provided details on the close relationship between the CIR panel work generally and the PCPC, as well as the talc review itself. Other documents available for review confirm the close relationship (*e.g.*, IMERYS 329339 through 329342; IMERYS315001; IMERYS320614; IMERYS281069; IMERYS281536; IMERYS283501; IMERYS322846; IMERYS298968; IMERYS065205; IMERYS118788; PCPC_MDL00103539; PCPC_MDL00009859; PCPC_MDL00009893; PCPC_MDL00009914; PCPC_MDL00009950). This is an important consideration in this case given the role that the CIR

plays in cosmetic safety assessments, assessments that are used by manufacturers to assert that their ingredients are safe as required by FDA.

86. Testimony and admissions from PCPC corporate representatives including exhibits to their depositions, are relevant to my opinions because they outline the level of influence on the purportedly independent processes for talc safety assessment by the CIR. To start, the PCPC's president is the chairman of the CIR steering committee that is responsible for choosing the experts that are on the CIR panel, including the talc review in 2013 (deposition of Dr. Loretz pages 842-845; IMERY5118788; trial testimony of Dr. Andersen dated 8/10/2018 at pages 3130-3031). The CIR review documents are written not by the expert panel but by CIR staff, who are employees of the PCPC (PCPC0004567; IMERY5118788; trial testimony of Dr. Andersen 8/10/2018). The CIR panel scientists are a standing committee, meaning that the scientists involved do not change that much from review to review, regardless of the issues to be addressed (deposition of Dr. Linda Loretz pages 842-845; trial testimony of Dr. Andersen 8/10/2018 pages 3132-3133). This is important because the issues related to talc safety are not the typical issues linked to cosmetic ingredients. For most cosmetic ingredients, the issue is not migration internally after perineal application or even use of large amounts of product that can easily suspend in air with each use. Additionally, much of the data that was important in the evaluation of talc as an ingredient in body powders and perineal dusting was human epidemiological data. Yet, the expert panel reviewing talcum powder products and talc as an ingredient in those powders did not include anyone with specific expertise in the unique exposure issues presented or expertise in epidemiology (deposition testimony of Dr. Loretz pages 781, and 838-842). All CIR panel members are paid through the PCPC which in turn is funded by industry, including Johnson & Johnson and Imerys⁵⁹. In fact, records show that many of the CIR panel members made tens of thousands of dollars each year that they served on the CIR panels (deposition testimony of Dr. Loretz pages 964-974), and that Johnson & Johnson and Imerys were major sources of funding for the PCPC (deposition testimony of Dr. Loretz pages 829-834) and, consequently, the CIR panel activities. The CIR review of talc

⁵⁹ Although Imerys is no longer a member of the PCPC (see deposition testimony of Dr. Loretz), Imerys was a member of the PCPC during the years that talc safety was at issue (1980's, 1990's, 2000's) and during the time of the CIR review of talc (2010-2013). See also IMERY5311275.

was initially started in 2009 but was put on hold for three years before beginning again in 2012 (trial testimony of Dr. Andersen dated 8/10/2018 page 3148).

87 Another example of influence on the FDA comes from the industry's response to the filing of two Citizen's Petitions related to adding a cancer warning to talcum powder products. Before continued discussion of the CIR process and industry influences, these events should be examined. This was discussed in the deposition of Dr. Linda Loretz on October 1, 2018.

88. Two Citizen Petitions were filed related to cosmetic talc products, one in 1994 and a second in 2008. In 2014, the FDA finally issued a response to those Petitions. In my experience, this is a very long time to wait for an FDA response. As background, the Citizen's Petition process is one that anyone outside of the FDA can use to ask FDA to take, or refrain from taking, an action related to any of the products regulated by FDA (21 CFR Part 10). The two Citizen Petitions were filed by the *Cancer Prevention Coalition*, and both related to adding a cancer warning to cosmetic talc products. In the case of the 1994 Petition, Dr. John Bailey, then Acting Director of the Office of Cosmetics and Colors within CFSAN at FDA, responded to the November 1994 Petition on July 11, 1995. Dr. Bailey stated that FDA had not been able to reach a decision on the Petition within the first 180 days of the filing (as required by the regulations) and the reason given was "*because of the limited availability of resources and other agency priorities*" (P-240). In the case of the 1994 and the 2008 Petitions, the FDA did not formally respond to the Petitioner until April 1, 2014 (P-47). The FDA's 2014 response indicated that FDA was not requiring addition of the specific cancer warning requested by petitioner.

89. In support of my opinions regarding the influence of industry on FDA's actions are the following accounts. In July 1994, six months after the filing of the first Citizen's Petition, a meeting sponsored by both FDA and industry (including Defendants in this case) was held that focused on the safety of cosmetic talc. A delegation from PCPC (staff of the PCPC, members of the organization, as well as consultants) met with representatives of the FDA (John Bailey⁶⁰ and

⁶⁰ This is the same John Bailey that a few years later leaves FDA and becomes a senior staff member of the PCPC.

Ron Lorentzen) and representatives of the NTP (Dr. Gary Boorman⁶¹) to discuss the NTP talc study data (JNJ000016687 through 688). Contained in the minutes to that meeting, PCPC reported that FDA admitted they were under pressure from within the agency to fully investigate the association between talc and ovarian cancer. Topics of discussion at the meeting were directed towards the use of the NTP study tissues for further analysis to help “reduce uncertainty about human risk”, whether it was feasible to analyze rodent tissues for the presence of talc particles, whether if analytical procedures for rodent tissue analysis were set up by FDA/ NTP it would be feasible to analyze human ovarian tissue, and what issues or problems might be raised by such studies. Interestingly, the PCPC stated in the meeting minutes that the discussion around analysis of talc in the animal tissues “*seemed to dampen enthusiasm by Dr. Novotny for conducting analysis of human tissue*” (JMJ000016688). The only work product resulting from this meeting appears to be the NTP’s analysis of archived ovarian tissue samples from rats and mice that were part of the NTP study (Boorman *et al.* 1995; the paper was submitted in October 1994 to the journal *Regulatory Toxicology and Pharmacology* and the concerns with this journal regarding talc safety is discussed below in paragraph 91). No work on human ovarian tissue analysis appears to have been initiated at this time.

90. The influence of industry on FDA actions was evident in the early 2000’s during the time when the NTP was considering the addition of talc to the Report on Carcinogens. In an e-mail dated 17 October 2000 (JNJ000013664 through 665), the PCPC was discussing the NTP’s recent draft background document on talc wherein the NTP scientists concluded that “*non-asbestiform talc is reasonably anticipated to be a human carcinogen*” and proposed listing the ingredient in the 10th Report on Carcinogens (RoC). This e-mail was directed to gathering funding commitments from industry to undertake actions aimed at stopping the listing proposed by NTP. This e-mail was followed by further communications on same topic later in October of 2000 (IMERYS303895 through 898) where industry representatives discussed experts that could assist in their efforts but where they also acknowledged that a new study had been published concerning the mortality of German rubber workers that had been exposed to talc and asbestos dust (combined dust exposure) where the results were stated to be “*not very good for the talc industry.*” The issue

⁶¹ Other NTP staff were there as well, as were a pathologist from the University of North Carolina (there to discuss analysis of human tissues in a future study) and an epidemiologist from NIEHS.

was stomach cancer mortality was important because, as the employee of Luzenac Europe⁶² explained, an internal study that the company had failed to publish also found an association between talc dust and stomach cancer; this information would not have been available to the FDA or the NTP. In an e-mail dated February 5, 2001, PCPC again was discussing the NTP process and the need to “pressure” the NTP to include Dr. John Bailey in its Executive Committee meeting, where it would be decided whether to accept the recommendations for a listing of talc in the 10th RoC. Note that, as discussed in more detail in paragraphs 94-96, NTP deferred the listing of talc as part of the 10th RoC.

91. Industry influence on FDA actions also was evident in 2008. On May 8, 2008, the PCPC attended a meeting with FDA to discuss the FDA response to the 2008 Citizen’s Petition (PCPC0061912 through 916⁶³). The meeting minutes state the meeting’s purpose: “*The Council requested the meeting solely to present scientific data to support the safety of talc and at the request of the Talc Interested Party.*” (PCPC0061912). A review of the minutes to the meeting show that the PCPC and other industry representatives failed to provide FDA with accurate description of their knowledge of cosmetic talc safety; examples would be their knowledge that US samples of cosmetic talc were not asbestos-free (some asbestos had been detected), and the issues behind NTP’s failure to list talc in its *10th Report on Carcinogens*. An email dated November 3, 2008, reveals Kathy Wille, Senior Director, Scientific and External Regulatory Policy, Product Stewardship, from Johnson & Johnson, had another interaction with FDA later in 2008. The e-mail states: “*had a side conversation with a key figure from the FDA cosmetic group that is responsible for responding to the Citizen’s Petition.*” The email further states: “*He indicated that the FDA would rule against the petition and would not require warning labels on cosmetic products. But the FDA is looking for **scientific support** from industry that will help justify their position. She suggested that there is a collective group working to have comments submitted to the FDA.*” (IMERYS 250983; IMERYS 281179). [**emphasis added**] In her 2021 deposition testimony, and affidavit executed in 2018 (affidavit of August 24, 2018; DX-1097), 10 years after this reported encounter, Kathy Willie denied that she had such a side conversation with FDA. On

⁶² This company was a sister company to Luzenac in the US which was a predecessor to Imerys.

⁶³ At the meeting were PCPC employees including Dr. John Bailey, formerly head of the FDA’s Office of Cosmetics and Color, and Dr. Linda Loretz, Dr. Kathy Wille, an employee of Johnson & Johnson, Dave Mallon an employee of Unilever, and Craig Bernard a Shirpal Shirma, and two employees of Rio Tinto (Imerys) that joined by phone.

July 21, 2009, the PCPC submitted comments on the Petitions to FDA (PCPC_MDL00015494; P-342). A review of the cover letter for the comments reveals that Dr. John Bailey, the same Dr. Bailey that was Acting Director of the Office of Cosmetics and Colors in 1995 and that responded to the first Petition by the Cancer Prevention Coalition, signed the 2009 letter as an employee of the PCPC. The letter was accompanied by a report prepared by Dr. Michael Huncharek and Dr. Joshua Muscat, consultants that had been hired by the PCPC to prepare a response. The defendant's response to the Citizens Petition contained misleading and inaccurate information, including that asbestos had been eliminated from talc which was an issue that was of concern to the FDA (see deposition of Dr. Linda Loretz).

92. Other documents reveal that Dr. Huncharek and Dr. Muscat had been working as consultants for Johnson & Johnson and Imerys for years (*e.g.*, JNJ000377405; JNJ000375565; JNJ000391641; deposition of Dr. Muscat dated September 25, 2018), providing the companies and/or the PCPC with consulting services related to talc and cancer risk as part of the NTP process in 2000 and 2005 and the IARC process in 2006 (see deposition testimony of Dr. Nicholson dated July 26, 2018; deposition testimony of Dr. Linda Loretz, Ph.D. October 1, 2018; deposition testimony of Dr. Muscat dated September 25, 2018, among others), as well as the talc Citizen Petition response process. Another document shows that in May 2009, PCPC members, including Johnson & Johnson and Imerys, met with FDA to discuss their comments before they were submitted in July 2009 (PCPC0028174-28176; JNJ000092018), even though FDA denied the *Cancer Prevention Coalition* the opportunity for a public hearing to discuss their scientific evidence that the Petitioner had requested both in 1994 and in 2008. The failure of FDA to afford the Petitioner a public hearing and request a more detailed examination of the Petitioner's scientific evidence to elicit a response to questions raised about talc safety in 1994 and in 2008 resulted in a process wherein industry was the sole source of information.

93. The evidence reviewed shows that the FDA did not hold a public hearing which would have allowed for more detailed input from scientists outside of industry. Moreover, as discussed above in some detail, the FDA was not, and has not even today, provided with all available evidence of the existence of the presence of toxic constituents such as asbestos in cosmetic talcum powder products. As a result, it is my opinion that the conclusions reached by

FDA in its 2014 response were not based on an accurate and complete understanding of the composition of talcum powder products. In addition, evidence shows that the FDA was not fully informed about the key role that certain industry consultants had played in generating some of the scientific studies and review papers that industry has used to support their assertions regarding the safety of talc. For example, the 2003 paper by Huncharek and colleagues (Huncharek *et al.* 2003. *Anticancer Res.* 23:1955-1960) failed to acknowledge that industry had provided support for their work, while later papers failed to acknowledge the full list of industry sponsors of their work (*i.e.*, Huncharek *et al.* 2007. *Eur. J. Cancer Prevent.* 16:422-429; Muscat and Huncharek. 2008. *Eur. J. Cancer Prevent.* 17:139-146; Huncharek and Muscat. 2011. *Eur. J. Cancer Prevent.* 20:501-507; see deposition testimony of Dr. Nicholson dated July 26, 2018). A 2005 response written by Dr. Muscat and Dr. Huncharek to critique the work of Dr. Cramer (Muscat and Huncharek, 2005) also failed to disclose the financial relationship between his work and industry (JNJ000368327; see depositions of Dr. Nicholson and Dr. Loretz). Related activities included the work of Huncharek and Muscat with respect to critiques of Dr. Cramer's work on the talc and ovarian cancer issue. An e-mail dated 30 September 2008 from Dr. Muscat to employees of Johnson & Johnson (JNJ000368327) reveals that Dr. Muscat clearly understood the importance of Dr. Cramer's positive study results concerning the association between genital talc use and ovarian cancer. The e-mail also addressed the data from the Nurse's Health Study (abbreviated as "NHS" in the e-mails), a cohort study which was described as a major reason why IARC in 2006 failed to assign a rating higher than "2B" to talc. Despite the evidence of an association seen in the Cramer study Dr. Muscat chose to ignore the Cramer results and presented a one-sided presentation of the scientific evidence to the FDA.

94. Prior to the CIR review of talc, there were significant events in the 1980's and early 1990's that triggered the need for a safety assessment of the products. The NTP had performed cancer studies in mice and rats in the 1980's that were published in 1993 (NTP, 1993; the report was discussed in detail above). In addition, by 1993, several scientific and/or epidemiological studies had appeared in the scientific literature linking perineal talcum powder product use with ovarian cancer in women (*e.g.*, Henderson *et al.* 1971; Cramer *et al.* 1982; Hartge *et al.* 1983; Whittemore *et al.* 1988; Booth *et al.* 1989; Harlow and Weiss, 1989; Harlow *et al.* 1992; Chen *et al.* 1992; Rosenblatt *et al.* 1992). As a result, a workshop was held in 1994 that was sponsored by

industry and the FDA (PCPC_MDL00026142; PCPC_MDL00028481; PCPC_MDL00028665; PCPC0072694; PCPC0075364; P-14). FDA's opening remarks at the workshop indicated that the FDA was wanting input on the "*validity and significance of the existing knowledge regarding the safety of cosmetic talc*" (Carr, 1995). The workshop was run by a group known as the ISRTP, the *International Society for Regulatory Toxicology and Pharmacology*. The ISRTP has been described as "*an association dominated by scientists who work for industry trade groups and consulting firms*" (Michaels, 2008; Michaels, 2020). Sponsors of the organization in the past have included major tobacco companies, chemical companies, and drug manufacturing companies (Axelson *et al.* 2003). The ISRTP also publishes a journal (*Regulatory Pharmacology and Toxicology*) and as pointed out by Axelson and colleagues (2003) the articles published often failed to list complete conflicts of interest disclosures. As a result, the ISRTP's activities have been questioned in terms of the level of industry influence that exists (Axelson *et al.* 2003).

95. The ISRTP talc workshop was held in 1994 (January 31 to February 1). The minutes to the meeting are available for review as are the papers that were published after that meeting in the ISRTP journal (1995; volume 21; pages 211-260). One day of the meeting was devoted to the issues related to the NTP cancer studies with talc and the issue of mechanisms of lung carcinogenesis (January 31, 1994), while the second day was devoted to the epidemiological data that had accumulated with respect to talc exposure in women and ovarian cancer and the issue of talc migration (February 1, 1994). Industry-sponsored scientists were among those attending and making comments during the meeting (P-0017). My review of the minutes to the workshop (PCPC0076689-76908; JNJ000008704-8864) as compared to the published summary of the workshop (Carr, 1995) reveals important differences in the actual statements made by scientists at the meeting and the published paper. The paper acknowledges that not all presentations were published. The workshop attendees are listed by Dr. Carr (Carr, 1995) and included 109 participants. At least 67 were from industry or were consultants to industry. Other participants were from government agencies (25 participants) and from academics or public interest groups (17 participants). Key differences in the minutes versus the published summary of the meeting included the fact that not all participants were present at the end of the meeting when the group discussed the workshop findings. Contrary to the statements in the Carr publication regarding "*unanimous assessment*" (Carr, 1995), the statement made on the second afternoon of the

workshop was as follows: *“It is not our intent, certainly not mine to strive for consensus, either as a unanimous consensus or a partial consensus which I understand you have to have to use now in describing a consensus...”* (JNJ000008843). Questions were raised by scientists at the meeting on the first day related to the fact that the animal data had limitations but that it still had relevance in terms of raising questions about the ability of talc to cause lung injury that could lead to cancer. On the second day, one speaker, Dr. Austin, indicated the epidemiological data provided some evidence of an association between talc and ovarian cancer (JNJ000008727). Then, Dr. Brown, another presenter, discussed the issue of talc migration to the ovaries and specifically stated *“the summary of my conclusions is that I believe it can”* (JNJ000008734)). In contrast, the Carr publication states: *“Following a presentation by Dr. Brown (University of Wisconsin), the discussion made it clear that available histologic and physiologic studies provide no basis to conclude that talc can migrate to the ovaries from the perineal region”* (page 215 of Carr, 1995). Thus, based on the large amount of information that was not discussed at the ISRTP workshop but was known to industry, it is my opinion that the Carr publication fails to provide an accurate and complete description of the state of the science with respect to talc safety in 1994. Moreover, an important outcome of this workshop was that the signal of talc and human cancer risk existed and could not be ruled out based on discussion at the workshop.

96. Additional evidence which supports my opinions comes from documents describing the industry response to the 1993 NTP publication of findings on talc and cancer in rodents, wherein the NTP concluded that talc was carcinogenic in animals. PCPC along with industry members re-activated the group known as the Talc Interested Party Task Force (*e.g.*, P-14; P-83; P-57; JNJ000016687 through 688). The Talc Interested Party Task Force was first established in the 1970's and reconvened in response to the publication of the paper by Dr. Cramer (Cramer *et al.* 1982), where use of cosmetic talc had been linked with ovarian cancer (P-0845). At this time, the group was led by Johnson & Johnson and the talc ingredient supplier Imerys. Documents from that time show that the goal was to mount a defense strategy around talc and to ensure that the products continued to be sold without regulation (*e.g.*, P-57; P-122; P-86; P-87; P-88; P-90; P-20; JNJ000016687 through 688). Yet, at least in the case of Johnson & Johnson, an outside consultant that had worked with the company for years on talc issues (Dr. Wehner) had suggested in 1994 that studies be performed to answer questions about talc safety, specifically with

respect to the risk of ovarian cancer (P-0435). From my review of the depositions and documents, there is evidence that industry had no interest in sponsoring any new research or did not want to spend the money on such research (P-32, deposition of Dr. Linda Loretz). As previously mentioned in paragraph 21 (above) it is the manufacturer's duty to conduct whatever testing is necessary to ensure the safety of their products. Evidence in this case shows that Defendants failed to perform such testing, despite awareness of safety concerns with cosmetic talc.

97. In formulating my opinions, it was relevant to consider evidence surrounding the activities by industry in the 2000's when NTP was considering whether or not to classify and list talc as a carcinogen as part of its Report on Carcinogens process. As of 1978, Section 301(b)(4) of the Public Health Service Act, as amended, requires that the Secretary of the Department of Health and Human Services (DHHS) publish an annual report on substance use and abuse. The Report on Carcinogens (RoC) is a report that lists all substances that are known to be human carcinogens or may reasonably be anticipated to be human carcinogens. As discussed on the NTP website⁶⁴, the first RoC was published in 1980, and since that time, the process has evolved in terms of the way that reviews are performed. In the early RoC process (up through the 7th RoC in 1994), there were formal listing criteria and two categories ("*known human carcinogen*" and "*reasonably anticipated to be a human carcinogen*") that were determined based on evaluation of cancer studies in humans and/or experimental animals. Starting with the 8th RoC process, the criteria for listing were expanded to include consideration of all relevant information such as mechanistic data. During the period that talc was reviewed as part of the 10th RoC in 2000, the review process included two federal review groups providing initial input on listing recommendations, followed by review by the NTP Board of Scientific Counselors Subcommittee that provided input on listings in a public forum, giving additional opportunities for public and/or industry input. As a result, the first two reviews undertaken were by government scientists and free from outside influence, while the last step in 2000 involved public input and review by a Board that included members from industry (as discussed in more detail below).

98. Deposition testimony and documents show that, in the context of my opinions that industry undertook significant efforts to influence regulatory bodies and the science concerning

⁶⁴ <https://ntp.niehs.nih.gov/pubhealth/roc/history/index.html>

the safety assessment of talcum powder products, the Center for Regulatory Effectiveness (CRE) played an important role. Based out of Washington, DC, the CRE is a “consulting firm” (<http://www.thecre.com/about.html>; C&M-LUZ 00013326; IMERYS 226115). The CRE’s primary purpose is to provide advice to companies and to intervene on regulatory issues that threaten their business (IMERYS 226115). With respect to talcum powder products, documents show there were two individuals from CRE that were involved: the company’s founder and owner, James “Jim” Tozzi and William “Bill” G. Kelly, Jr. Imerys initially retained the CRE in 2000 to assist with the 10th RoC process at NTP (IMERYS 100237) and the CRE’s consulting work with Imerys continued for more than a decade. Yet, documents show that the CRE represented themselves as being an “*independent*” organization and “*not affiliated*” with any particular industry, company, or other entity. (IMERYS 100151 and MDL_KELLY00014222). Documents also show that CRE efforts on behalf of Imerys led to sufficient confusion regarding the definition of talc such that NTP’s Executive Committee reversed the scientists’ classification of talc as a carcinogen (IMERYS 330351, IMERYS 303828, IMERYS 110806, IMERYS 209930). CRE efforts on behalf of industry continued with their interaction with the CIR and the production of the 2013 CIR safety assessment of talc (IMERYS 226115; MBS-CRE000031, MDL_KELLY00017550, MDL_KELLY00014222, MBS-CRE000271).

99. There had been 15 RoC processes up to 2021, the 15th RoC being published in December 2021. No additional RoC reports were publicly listed at the NTP website as of May 2024. Talc was considered as part of the 10th and 12th RoC processes. The 10th RoC meeting where talc was discussed was held in 2000, while the 12th RoC meeting was held in 2005. The 10th RoC deferred action to list talc as a carcinogen, citing a need for additional information; the 12th RoC also deferred action to list talc. It is important to note that the NTP RoC nominated talc for consideration for listing in the 10th RoC based on a review of the available data by a body of scientists without input from industry, and without any direct interaction with other industry groups or representatives with a conflict of interest, consistent with the procedures set forth by IARC for its cancer reviews (IARC, 2006). It is also important to note that a review of the minutes of the 10th RoC indicates that even though the only public comments made to the panel were from industry representatives, many of the reviewers supported listing non-asbestiform talc as reasonably anticipated to be a human carcinogen (IMERYS 039060 through 085). During the 2000

NTP review of talc for listing in the 10th RoC, it is my opinion that Imerys, the PCPC, and Johnson & Johnson made efforts to influence the process and prevent talc from being listed as a carcinogen (*e.g.*, P-0255; P-0012; P-0013; P-0089; P-0317). Documents show that Imerys, with the full knowledge of Johnson & Johnson and PCPC, hired the Center for Regulatory Effectiveness (CRE) in 2000 to submit comments to influence the RoC process without disclosing that defendants coordinated and were directly involved in both the strategy for and the drafting of those comments (IMERYS024243; IMERYS-A_0024244; JNJ 000242897; JNJ 000404803; JNJ 000001699; PCPC0072893; NTP Summary Minutes, Dec. 13-15, 2000). This effort to influence the process continued into 2001 when the Executive Committee of NTP met and made the decision to defer talc even though the scientists that had reviewed talc had overwhelmingly voted to list talc as a carcinogen (*e.g.*, IMERYS024367; IMERYS 303895-898; P-27; JNJ000013664; JNJ000404511-512; PCPC0066630-672; IMERYS-A_0024411; IMERYS303842; IMERYS288570; IMERYS239852; IMERYS239750; IMERYS239749; IMERYS026529; IMERYS024243; JNJ000008350; JNJ000008344; JNJ000000636; JNJ000368187; JNJ000404425; NTP minutes 2000; IMERYS303828; IMERYS179104; IMERYS208830; IMERYS-A_0024244; PCPC0035777; PCPC0066630). At least by 2002, evidence shows that Imerys was aware of the consequences of listing talc as a carcinogen in terms of product liability issues (P-26; P-3). Evidence shows that industry was aware that, the NTP was more vulnerable to such influence than other bodies such as IARC (P-27). Additional documents provide evidence that efforts to influence the NTP cancer listing process by industry continued in 2004-2005 when talc was scheduled to be considered as part of the 12th RoC process (JNJ00003646-348; IMERYS288692; IMERYS271234; IMERYS035406; JNJ000003436; JNJ000003472; JNJ000375565; JNJ000369203; IMERYS287089; IMERYS324762; IMERYS 236653).

100. IARC has reviewed talc twice, and its conclusions were published first in 1987 and again in 2010.⁶⁵ In contrast to the CIR review process which involved a much more cursory review of the science behind over 5000 cosmetic ingredients in the 40 plus years of its existence and only 12 were found to be unsafe for use in cosmetics, IARC was founded in 1965 and in that time has published 122 volumes describing the cancer hazard posed by 1016 different compounds. Of those

⁶⁵ IARC's website indicates that IARC will be evaluating talc and carcinogenicity again in June of 2024 (<https://monographs.iarc.who.int/news-events/meeting-136-talc-and-acrylonitrile-is-announced/>).

compounds reviewed by IARC, 120 were found to be “*carcinogenic to humans*”, 82 were found to be “*probably carcinogenic to humans*”, 302 were found to be “*possibly carcinogenic to humans*”, 501 were found to be “*not classifiable as to its carcinogenicity to humans*”, and one compound was found to be “*probably not carcinogenic to humans*”⁶⁶. IARC focuses solely on the issue of cancer hazard and prioritizes its reviews based on compounds where evidence has accumulated indicating there may be a cancer hazard.

101. In the first assessment of talc (IARC, 1987), the panel met in 1986 and concluded that there was sufficient evidence for human carcinogenicity for talc containing asbestiform fibers (asbestos and fibrous talc) but inadequate evidence for talc not containing asbestiform fibers. Talc with asbestiform fibers was listed as Group 1 (known human carcinogen); talc without asbestiform fibers was listed as Group 3 (not classifiable as to human carcinogenicity). The IARC classification system used to define evidence of carcinogenicity was discussed by Johnson & Johnson in a 2002 communication from Bill Ashton, an employee of Johnson & Johnson:

*“IARC classified crystalline silica as a potential human carcinogen in 1986. That same year they reviewed talc and concluded there was “inadequate evidence” to classify talc as a potential human carcinogen. **That was not a “non-carcinogen classification”**; it just means they did not have enough evidence to conclude that talc was a potential carcinogen. In 1986, they also concluded that “talc containing asbestiform fibres” was a known human carcinogen.” [emphasis added]*

In 2006, IARC again considered the classification of talc as a carcinogen. The working group considered a large body of data available up until 2006, which included a large group of human epidemiological studies examining the risk of ovarian cancer with perineal talc use in women. Although industry was aware that the IARC process was less political (P-27), evidence shows that, consistent with my opinions regarding industry’s influence on the talc regulatory processes, industry still initiated efforts to influence the science surrounding talc and cancer risk (JNJ000003914-315; JNJ000004015-4019; JNJ000003969; JNJ000369087; JNJ 000003911; JNJ 000003969). These efforts included having Dr. Muscat, a consultant to industry (IMA-NA0000571; JNJ000369543; deposition of Joseph Muscat; Muscat000001494; Muscat000001204) attend as an observer and to attempt to influence reviewers with his comments.

⁶⁶ <https://monographs.iarc.fr/agents-classified-by-the-iarc/>

Other documents provide additional information about the attempts by industry to influence the IARC process in 2006 (e.g., P-0650; P-0204; P-0035; WG-IMA-NA0001554). It is notable that the IARC panel, with less chance of outside influence being asserted, listed talc without asbestiform fibers as a carcinogen (Group 2B; possibly carcinogenic to humans). Following the IARC classification of talc, Imerys elected to add a cancer listing to its MSDS sheet for talc as a possible human carcinogen. Johnson & Johnson has refused to do the same on its MSDS for finished products (JNJ000390337-338; JNJ4T5_000004521-522). The failure of Johnson & Johnson to warn consumers, and even workers that are involved in handling of their products, about the cancer risk associated with use or exposure to talcum powder products is a public health concern. In addition, when talc was listed as a possible human carcinogen by IARC in 2006, documents show that industry continued to promote a message about talc safety by recruiting scientists to publish articles that raised doubt about the link of perineal talc use and ovarian cancer (e.g., P-78; P-92).

102. Returning now to consideration of the CIR process for talc in 2012-2013, documents suggest that industry was intimately involved with the CIR process and its review of talc safety. Important details related to the influence exerted by industry on the overall CIR process as well as the talc review itself is found in the trial testimony of Dr. Alan Andersen (dated August 11, 2017). Dr. Andersen was in charge of the CIR process and was an employee of the PCPC. Dr. Andersen was responsible for implementation of the talc CIR review process. His testimony and the accompanying documents showed that at least two of the CIR expert panelists that he allowed to participate had conflicts of interest that were not publicly disclosed, and that Mr. Kelly of the CRE provided assistance to the CIR during its talc review. Some of the language in the final CIR talc review documents was copied directly from comments made by the CRE. Additionally, Dr. Andersen was not aware of the fact that the CRE had been hired by Imerys and the talc industry to provide comments to CIR. Additionally, evidence shows that in submitting comments to the CIR, Mr. Kelly of the CRE claimed that *“The Center for Regulatory Effectiveness is not representing a particular company or industry segment in filing these comments [,]”* even though he was working for Imerys at the time (IMERYS 062429). Then, before the review even began, he commented that CRE had established a *“strong relationship with the Cosmetic Ingredient Review.”* (IMERYS 226115). Monice Fiume of the CIR staff told Mr. Kelly in 2011, before the review began, *“that*

CIR would welcome any input from industry on the review at any time.” (IMERYS 065205). Further evidence shows that CIR staff and not the expert panel itself, wrote the talc safety assessment report, and then provided the expert panel with that review as well as comments on the document that had only been made by industry or by consultants to industry (PCPC0004567; IMERYS14817; IMERYS118788; IMERYS065205; IMERYS315001; IMERYS320614; IMERYS281536; IMERYS283501; IMERYS322846; IMERYS298968).

103. It is my opinion as well that information contained in other industry documents, reveal industry efforts to influence scientists and regulators making decisions about talc and its human health risks, were not limited to interactions with the NTP, the FDA and the IARC panel (JNJ000024397; JNJ000379382-384; IMERYS-A_0005090; JNJ000003405; JNJ000381275-276; P-0021; P-0030; P-0031).

VIII. Talc’s Human Health Risks and Regulatory Concerns

104. A review of scientific literature and internal company documents from Imerys, Johnson & Johnson, and PCPC shows that the defendants were aware of the human health hazards associated with talc powder products for many decades. Given the presence of asbestos, fibrous talc, nickel, chromium, and cobalt in the talc body powders manufactured by Imerys and Johnson & Johnson, it is my opinion that a significant human health risk was identified as a hazard related to talcum powder products use at least by the 1940’s. These risks included a risk of cancer with exposure to constituents of talcum powder products, and even death with acute inhalation of large amounts of the powder. The following chronology supports my opinion that there is adequate evidence that talcum powder product use poses a hazard to human health.

- By 1940, the scientific literature contained studies showing that mineral dust exposure, including exposure to talc and asbestos, was associated with lung diseases that could be fatal, and that talc used to manufacture body powders contained both platy talc and fibrous components, including tremolite. Studies by Johnson & Johnson scientists themselves in the 1940’s had identified talc as a hazard to human health (Eberl *et al.* 1948).
- By 1950, the scientific literature contained studies showing that talc was associated with adverse tissue reactions in both humans and animals, that the fibrous component of talc was of concern, that exposure to talc in the cosmetic industry itself could produce lung

disease, that lung disease due to talc and asbestos was similar, that tremolite dust was an industrial hazard in terms of lung disease, and that even small doses of talc from surgical gloves was linked with adverse tissue reactions, even being described as “*a serious menace in surgery*” (Saxen and Tuovinen, 1947) and as posing a “grave danger” (Eberl *et al.* 1948).

- By 1952, Johnson & Johnson was aware of the adverse tissue reactions linked to talc powders, including the dangers of inhalation of talc (U.S. Patent 2,626,257), even filing a patent for a replacement for talc as a medical dusting powder.
- By 1954, the scientific literature included an adverse report of death in a 10-month old infant due to asphyxiation after aspiration of a large amount of baby powder. It should be noted that reports of such deaths and serious injuries in children continued to occur into the 1960’s and 1970’s. In 1966, the medical community was concerned about the risks of asphyxiation and urged that talcum powder be withdrawn: “*In conclusion, it is strongly urged that talcum powder be removed from the environment of children and the traditional association of talcum powder and babies be abandoned. It has no medicinal value; wherever placed it serves as a foreign body; and at least three deaths and an unknown morbidity have resulted from this silicate powder.*” Later in 1969, another physician recommended the following: “*The widespread ignorance of the dangers of talc aspiration is not surprising, and it is my opinion that these dangers should be better publicized. The direct means of accomplishing this would be a warning statement on each container.*” (Moss, 1969).
- By the mid 1950’s, the majority of scientists believed that asbestos could cause lung cancer, and likely other forms of cancer, in humans (Doll, 1955). Evidence for a link of asbestos exposure with lung disease, including lung cancer, was available by the 1930’s.
- By the 1950’s the scientific literature indicated that asbestos was present in talc, including milled powders (*e.g.*, Dreessen and Dalla Valle, 1935; Millman, N. 1947; Hogue and Mallette, 1949; Schepers and Durkan, 1955). Evidence shows that even today, talcum powder products, including products manufactured and sold by Imerys and Johnson & Johnson included asbestos, fibrous talc, nickel, chromium and cobalt.
- In 1960, the scientific literature included a paper describing the link of ovarian cancer with asbestos exposure (Keal, 1960). Given that it was known that asbestos was present in talc powder, this paper provided notice that the talcum powder products sold by Johnson &

Johnson posed a risk for ovarian cancer as well as lung cancer. Further support for the association of ovarian cancer with exposure to asbestos also was provided in the 1960's (Graham and Graham, 1967).

105. Based on the knowledge available by the 1950's, it is my opinion that talcum powder products manufactured and sold by Imerys and Johnson & Johnson should have warned consumers about the toxic constituents, such as asbestos, fibrous talc, cobalt, nickel, and chromium, in their products and the effects that could be produced by exposure to talc dusts. It is noted that in the 1953 Johnson & Johnson patent, U.S. Patent No. 2,626,257 (filed May 21, 1952), statements warning of adverse human health effects are provided including the following statement: *"Even persons who were not subjected to internal application of talcum have suffered severely from it. Talcum in the respiratory tract is dangerous and has caused severe breathing difficulties to infants, hospital patients and nurses when used carelessly and/or permitted to contaminate the air in large amounts."* Although these statements were made in the patent documents, which may have been seen by lawyers and others involved in intellectual property evaluations, no warnings related to any adverse effect of talcum powder products was made available to the scientific and medical community, regulators, and consumers through statements on packaging of Johnson & Johnson talcum powder products until the 1980's (JNJ000450199-205). Even in 2021, despite the large body of data that has accumulated since the 1950's linking talcum body powder exposure with a risk of cancer, Johnson & Johnson talcum powder products failed to warn consumers about the risks of cancer linked to talc exposure.⁶⁷ It should be noted as well that with respect solely to the presence of toxic constituents in talc such as asbestos, fibrous talc, nickel, chromium, and cobalt, and as discussed above in paragraph 19, Johnson & Johnson's failure to list those talc constituents on its labeling would be consistent with the FDA's definition of a misbranded product as well as an adulterated product.

⁶⁷ Although Johnson & Johnson recently has indicated that their talc-based body powders will no longer be sold globally (see the Press Release by Johnson & Johnson dated August 11, 2022), the talc-based powder products already released to the market and sold were not recalled by the company. As a result, any bottles of Johnson & Johnson's Baby Powder or Shower-to-Shower that remained in the market or were in the homes of consumers in 2023 would not include a warning for consumers about the risk of cancer that has been associated with use of their product.

106. The issue of safety concerns related to talcum powder products and the failure of companies to warn consumers about serious adverse health effects is of particular importance in the case of a cosmetic product, such as Johnson's Baby Powder, Shower-To-Shower and Shimmer. This is due to the regulatory process in place in the United States related to cosmetics. Unlike the regulation of drugs, devices, and food additives, the responsibility for safety assessment of cosmetic ingredients and products is the responsibility of the cosmetic ingredient and product manufacturers, not the FDA. Cosmetics do not undergo any premarket approval process at FDA. As a result, it is the cosmetic manufacturer, and/or the cosmetic ingredient manufacturer, that is responsible for assuring that the products sold to the consumers, and the ingredients in those products, are safe for use (*Federal Register* 40(42) March 3, 1975). Moreover, there is no benefit assessment made for cosmetic products. In 1966, Johnson & Johnson was aware that their products were considered to have no health benefit (JNJNL61_000039194). This is consistent with the cosmetic regulatory paradigm that is only based on weighing risks of ingredients and products, not benefits.

107. Manufacturers of cosmetic ingredients and finished cosmetic products have a responsibility to continually monitor the scientific information that develops over time to determine if the risks associated with an ingredient, and/or a product, changes due to things such as previously unknown information, development of additional supporting information that may alter the existing safety profile of a product, and even identification of unanticipated safety concerns that can arise with real world use of products. In other words, the responsibility of the manufacturer does not end once an initial safety determination has been made.

108. As already discussed, the US regulation related to labeling of cosmetics and warnings is as follows (21 CFR 740.1(a)): "*The label of a cosmetic product **shall bear a warning statement** whenever necessary or appropriate **to prevent a health hazard that may be associated with the product.***" This statement means that the standard that must be met when deciding whether to add a warning to the label of a cosmetic warning is whether there is a possibility of a health hazard and that it could be prevented. In the current case, that "possibility" is of cancer occurring in humans using the body powders for genital dusting. The prevention issue would be related to warning consumers not to use the powders for genital dusting. As discussed in detail above, based

on the available scientific data as well as my education, training, and experience, it is my opinion to a reasonable degree of scientific certainty that Imerys and Johnson & Johnson should have initiated actions to add a warning to the labeling of talcum powder products at least by the 1950's that described the adverse health effects linked to talc body powder exposure. Specifically, a warning about serious tissue toxicity and the increased risk of ovarian cancer with use of talcum powder products should have been included on the product labeling. It also is important to note that my earliest report on the safety and regulatory concerns associated with Johnson & Johnson body powder products (dated October 5, 2016) focused on the addition of a specific ovarian cancer warning with genital talc use and discussed the need for a warning by at least 1982. Consistent with these opinions, my reports dated August 29, 2018, November 16, 2018, and June 30, 2021, as well as my deposition and trial testimony in 2018 and 2019, addressed questions raised regarding the need for warnings on Johnson & Johnson talcum body powder products in the period prior to 1982. The basis for my warning opinions is derived from additional review of many internal company documents that pre-dated and post-dated 1982 in conjunction with my review of additional publicly available studies and documents that were dated from the early 1900's through the 1970's.

109. In order to add warnings to a product label in the United States, the company must be aware of the risk, which is why I have outlined what was known and when it was known (discussed above in detail). A review of internal company documents, documents from Johnson & Johnson, Imerys, and the PCPC shows that talc ingredient manufacturers and the manufacturers of talcum powder products were following the published literature and were also intimately involved in the safety assessments of talc over the years (*e.g.*, IMERYS 052752 through 754; P-81; Shripal Sharma deposition dated 9/26/2012; John Hopkins depositions dated 10/26/2012, 8/16/2018 and 8/17/2018; and depositions of Dr. Linda Loretz). Thus, the defendants were at least aware for decades that ovarian cancer *may* be associated with the use of talcum powder products.

110. It is important to note that Johnson & Johnson has undertaken efforts to improve the safety of its products used on babies, which would include its talcum powder products. In 2012, Johnson & Johnson made the decision to remove certain harmful chemicals from its baby products including the IARC Group 2B carcinogen triclosan (see *e.g.*, P-38). This action conflicts with the

company's position on talc, also an IARC 2B carcinogen, where Johnson & Johnson did not include a warning to consumers about the risks associated with genital talc use. Then, in 2018, Johnson and Johnson initiated actions to overhaul its baby product line to be more "natural," by removing artificial ingredients and becoming more transparent in terms of the actual ingredients in its products, including Johnson's Baby Powder. These actions did not lead to removal of talc, or other constituents of its body powder, from its products and their products still failed to provide a warning to consumers about the cancer risk associated with talcum powder products. Instead, by using the word "natural" the companies are now suggesting an improved safety profile despite no substantive changes in the risks linked with the product. It should be noted that at this same time in 2018, other manufacturers of talc-based body powders had already added warnings to the labels of their talc body powder products related to the risk of cancer, even though Johnson & Johnson failed to take such action (*see* Appendix E). In May 2020, Johnson & Johnson stopped distributing its talcum body powder products in the United States and Canada; they did not recall the product from store shelves (*see* Press Release by Johnson & Johnson dated May 19, 2020)⁶⁸. Existing product continued to be sold. Finally, in August of 2022, Johnson & Johnson announced they would be transitioning to cornstarch globally for all their body powders (*see* Press Release by Johnson & Johnson dated August 11, 2022).⁶⁹

111. Another action that Johnson & Johnson had taken early on was developing an alternative line of body powders based on the use of cornstarch instead of talc. Johnson & Johnson investigated an alternative body powder product based on cornstarch instead of talc as early as the 1960's (JNJ000265536-538; *see* Cornstarch Fact Book JNJTALC000864509). Johnson & Johnson filed a patent in 1952 that issued in 1953 for medical dusting powders that were cornstarch-based powders and in that patent identified the significant toxicity associated with talc powders (U.S. Patent 2,626, 257). The text of the patent describes the toxicity of talc in tissue as a reason for finding a replacement. On February 21, 1964, a Johnson & Johnson Memo regarding cornstarch

⁶⁸ <https://www.jnj.com/our-company/johnson-johnson-consumer-health-announces-discontinuation-of-talc-based-johnsons-baby-powder-in-u-s-and-canada>

⁶⁹ <https://www.jnj.com/johnson-johnson-consumer-health-to-transition-global-baby-powder-portfolio-to-cornstarch#:~:text=August%2011%2C%202022%20%E2%80%93%2022As,be%20discontinued%20globally%20in%202023>

development states, “...*it replaced talc because it was found to be absorbed safely in the vagina whereas, of course, talc was not.*” [*emphasis added*] (JNJ000265536-265538) Throughout the 1960’s and 1970’s, Johnson & Johnson continued to develop cornstarch as a body powder product (e.g., JNJ000265482-483; JNJ000253830-832; JNJ000245901-903; JNJ000245744-748; JNJ000244094-095; JNJ000526750; JNJ000404860; JNJ000279507; JNJ000245762; JNJ000011150; JNJ000026987; JNJ000245678; JNJTALC000866104; JNJ00006987-7007). Important in this process was the fact that the company performed test marketing of a cornstarch Johnson’s Baby Powder product in 1977 and found that the cornstarch product “*has been accepted by the consumer as a formula replacement*” (JNJ000245679). In 1978, the FDA’s OTC Monograph for skin protectant products (i.e., body powders) listed cornstarch as Generally Recognized as Safe and Effective (GRASE) for use in OTC products (JNJ000470844-846; JNJ000348778) and even noted that cornstarch was recognized as being superior to talc in terms of safety and efficacy (JNJ000470846; JNJ000019415). Therefore, at least by the 1970’s, Johnson & Johnson had identified a replacement ingredient for its talcum powder products that they knew was safe and provided the desired cosmetic properties. With respect to the issue of talc as compared to cornstarch powders and ovarian cancer risk, one study has reported that cornstarch is “*not predicted to be a risk factor for ovarian cancer*” (Whysner and Mohan, 2000). With respect to alternative talcum powder products, Imerys has begun work to produce a synthetic talc powder product (Claverie *et al.* 2018; Imerys 2017-2018 Annual Report); such synthetic talc powder should be able to be produced such that it would be free of constituents such as fibrous talc, asbestos, and heavy metals. These actions by Johnson & Johnson as early as the 1950’s indicate that the company was aware that there was a safer alternative product, i.e., cornstarch-based body powders, that was also acceptable to their consumers. Yet, it was not until 2022 that Johnson & Johnson took action to replace talc-based body powders entirely with the cornstarch-based products.

112. With respect to Imerys specifically and this issue of warning consumers about risks linked to products, in another internal document (IMERYYS 284935 through 937), the importance of the public safety issues surrounding talc, and women’s health in particular, were acknowledged by industry. Documents support my opinion that industry was aware of the need to warn consumers of the cancer risk issue in 2006 (P-0033). Yet, no actions were taken to inform the consumer about

the risks associated with talc products. Evidence shows that Imerys began drafting a proposal to FDA wherein industry suggests voluntarily phasing out the production and sale of all cosmetic talc products used for consumer dusting powders that could reasonably be anticipated to be used by women for perineal applications and also to assist the FDA in developing a warning label for body powders containing talc that would warn of the danger of genital dusting (IMERYS 284935 through 937; P-341). Importantly, there is no warning statement on Johnson & Johnson talcum powder products that refers to the risk of cancer of any type, including ovarian cancer with genital dusting.

113. Johnson & Johnson has never placed a warning on its talcum powder products in order to inform consumers about the serious health risks associated with use of their products. The labeling is, and was, inadequate to inform consumers about the risks associated with use of its products, including the risk of cancer. Given that MSDS sheets are not supplied to consumers of talcum powder products, Imerys also failed to ensure that consumers were warned of the risk of cancer associated with genital talc use (IMERYS328096). Placing a warning on the talcum powder product labels would have been an important step towards informing consumers of the hazard associated with repeated use of the products for genital dusting. Given that products were not recalled from consumers, the product may still be in homes, or on the shelves in the United States. Moreover, the labeling for such talc-based powder products fails to warn consumers of the risk of cancer with genital application.

114. In a survey of the commercial market in 2018, I identified several talcum body powder products that have included a consumer warning about an increased risk of cancer. Attached in Appendix E to this report is a series of photographs of bottles of body powder that contained such warnings. For example, some of these product labels state: "*Frequent application of talcum powder in the female genital area may increase the risk of ovarian cancer*". This is an example of a warning being placed on talc-based body powder products that was consistent with 21 CFR 740.1(a) in the United States.

115. Evidence from other internal corporate documents support my opinions that the defendants were aware that talcum powder products may be associated with a health hazard, which would require a warning on defendants' products. Examples include:

- According to a February 1964 memorandum (P-343), a meeting was held among Johnson & Johnson scientists wherein the issue of talc safety is raised in the context of a discussion of the use of cornstarch as an alternative powder product. The memo stated: *"The largest commercial uses of Dry Flo [a cornstarch powder under development as a talc replacement at J&J] are in Vitamin A manufacture (5% in finished product) and as a condom lubricant where **it replaced talc because it was found to be absorbed safely in the vagina whereas, of course, talc was not.**"* [emphasis added]
- In 1966, in response to a publication in the scientific literature (Hughes and Kalmer, 1966), Johnson & Johnson's Dr. Hildick-Smith received a memorandum (JNJNL61_000039194) concerning Johnson's Baby Powder's hazards. Other evidence has shown that Johnson & Johnson routinely followed the published literature related to talc. In the memorandum, the author states *"Baby Powder represents the cornerstone of our baby product franchise. In addition, we have a large investment in a talc mine. I am concerned over the conclusion drawn in the article..."* Importantly, the issue of developing mechanisms to reduce the hazard is raised.
- In a July 9, 1971, memorandum (JNJ000284105-106), Dr. Hildick-Smith memorialized the discussion he had with Dr. Selikoff, an academic scientist who had raised questions with industry about the presence of asbestos in talc. Dr. Selikoff was proposing that a series of studies be carried out, studies that he was willing to perform, to answer critical questions about talc body powder safety.
- In a 1971 internal Johnson & Johnson memorandum (authored by Dr. Hildick-Smith; P-1186), the issue of talc migration from the vagina to the ovaries is discussed. The memorandum describes data that had been collected in women undergoing a hysterectomy where talc placed into the vagina was found to migrate to the ovaries; these data indicate that talc can move inside the body when particles gain entry via the vagina.

- In a March 27, 1972, memorandum (JNJ000468919), Dr. Hildick-Smith confirms that Tenovus Institute would be embarking on a research program to study talc and its relationship to cancer of the ovaries.
- In April of 1972, the National Institute of Occupational Health and Safety (NIOSH) reported that samples of Johnson & Johnson Baby Powder contained significant amounts of fibers (JNJ000260700). The fibers are not specified as being fibrous talc or asbestos. At this point in time, fiber exposure generally was known to pose a risk to human health.
- In a 1973 Johnson & Johnson document (P-1166), key employees discussed the fact that fibrous talc was present in their baby powder as well as the fact that the company could not rely on a “clean mine” approach as a *“a protective device for Baby Powder in the current Asbestos or Asbestos-form controversy.”* Defendants were aware that both the talc used to make body powder products and the talc powder products that they produced had fibers in them that were asbestiform in nature and even referred to these as fibrous talc. Also discussed in this document was the fact that one answer to the concerns over the presence of fibers in talc powder products was to replace the talc with cornstarch because *“by its very nature”* it *“does not contain fibers”* and *“it is assimilated by the body”*.
- A January 1974 memorandum (P-660) written by Johnson & Johnson captures the contents of a meeting held on January 16, 1974, with the Commissioner of the FDA regarding data on asbestos in talc that had been brought to the FDA’s attention in the early 1970’s. In the document Defendants stated: *“If the results of any scientific studies show any question of safety of talc, Johnson & Johnson will not hesitate to take it off the market.”* Despite Defendants suggested commitment in the 1970’s to actively monitor talc safety issues the company took no action to inform consumers of the potential safety concerns linked to talc body powder.
- A December 3, 1975, Johnson & Johnson memorandum (P-55) is titled *“talc in the ovaries.”* Hand-written review notes added by Bruce Semple of Johnson & Johnson raise the question of the company now being *“on notice re: the talc/ovary problem.”*

- In a 1986 Johnson & Johnson “*Technological Forecast*” document (P-9), the company admits that there are continuing health concerns with talc and the safety of cosmetic powders, and that the powders have no health benefit.
- A Johnson & Johnson document dated August 5, 1992 (P-10) described declining sales of Baby Powder, including talcum powder products, and the company’s desire to grow the powder franchise by targeting minority populations of women; this is a concern given that the same document acknowledges the link of the products with cancer.
- In a document from 1997 written by Johnson & Johnson’s own toxicology consultant, Dr. Alfred Wehner, Defendants were informed about false public statements being made by the PCPC regarding talc safety (P-20); yet, Johnson & Johnson did nothing to correct the false impression left by the PCPC’s statements.
- In a 1997 document, Johnson & Johnson downplayed the health risks of talc when it responded to media questions about its products (P-115); failing to acknowledge the role that industry played in the 1994 evaluation by FDA and the fact that reliable scientific evidence had raised a signal for cancer risk.
- In a 2000 document from Imerys files, results from a marketing survey discussed that “*the general public is not aware of any health issues regarding talc*” (P-24).
- In a 2000 internal Imerys e-mail, Richard Zazenski, a key Luzenac employee that was involved in responding to the talc safety concerns agrees with the NTP reviewers that the epidemiology studies are concerning, and the data is not dismissible. The e-mail also suggested that he may even agree with adding warning labels (IMERYYS 240341).
- A 2000 memorandum prepared by Burson-Marsteller for Johnson & Johnson announced the intent to only use cornstarch beginning December 1, 2000, and discontinue the use of talc in all consumer products (JNJ000404424 and JNJ000404425). Despite their marketing piece, Johnson & Johnson continued to use talc in their consumer body powder products for more than two decades (up until 2022).
- In a 2001 presentation by Steve Jarvis of Imerys, the adverse human health effects of talc are acknowledged. He states that “*there are some health issues with talc*”

based on finding for 20 years a “*persistent statistical link between the hygienic use of talc and ovarian cancer*” (IMERYS 178944).

- In a January 2, 2001 e-mail (P-317) from Rich Zazenski to Eric Turner (both employees of Luzenac, now known as Imerys), the two men discussed the NTP’s 2000 RoC process and how the industry “*dodged a bullet in December based entirely on the confusion over the definition issue*”, where the definition issue referred to the purity of talc that would have been used by women involved in the older epidemiology studies where asbestos was more likely to have been found in cosmetic talc products. The discussion went on to describe how this issue may be addressed by NTP such that cosmetic grade talc would be listed in the future as having limited evidence from human studies, a standard that would likely lead to a NTP listing of talc in the RoC. Thus, Defendants were aware of the human health hazards that had been linked to talc exposure through use of talc body powders.
- In a February 26, 2002, document (P-26), Mr. Zazenski described an outcome if talc without asbestiform fibers were to be listed as a carcinogen by NTP. The document addresses the issues surrounding the need to warn consumers about the cancer issue.
- In a series of e-mails in January 2005 (JNJ000390337-339), Johnson & Johnson employees discussed the fact that talc body powder product Material Safety Data Sheets (MSDSs) should include a listing for talc as a component(s) that “have been defined as a cancer-suspect agent by worldwide reputable agency”. Yet, in the same e-mail chain the response from another Johnson & Johnson employee was: “Do NOT send out any MSDS with this statement on it!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!” [the large number of exclamation points is in the document itself at JNJ000390337]
- In 2006, Imerys changed their talc Material Safety Data Sheet (MSDS) to add that IARC had listed talc body powders as “possibly” carcinogenic to humans (IMERYYS 188701-705) yet consumers were not provided the same information on product labeling.

- In a 2008 email Todd True, former Global Creative Director for Johnson & Johnson, Mr. True said: *“The reality that **talc is unsafe** for use on/around babies is disturbing. I don’t mind selling talc, I just don’t think we can continue to call it Baby Powder and keep it in the baby aisle.”* Fred Koberna, another Johnson & Johnson employee, responds, *“My understanding is that we introduced the cornstarch variant as an alternative to talc for use on babies. Due to the talc issue and some doctors recommending for moms not use powder on their babies, we don’t promote powder to moms.”* Mr. True responded, *“I am on a bit of a mission to strongly consider removing talc from the baby aisle.”* (JNJ000457161) *[emphasis added]*
- In a 2009 memo, Imerys criticized Johnson & Johnson for preferring to purchase talc based on cost rather than quality (P-560)
- In 2010, Johnson & Johnson made media recommendations for advertising its talc body powder products (P-374). In the document, Defendant discussed a key strategy and tactic to be *“target overweight women living in hot climates during key summery season”*. This recommendation was made despite evidence that the cosmetic warning standard for a possible human health hazard had been met for talcum powder.
- In two documents related to Johnson & Johnson’s pharmacovigilance assessments in 2012 through 2014 (P-882 and P-883), employees had determined there was a causal connection between talc body powder use and certain cases of ovarian cancer reported to the company, but the decision was made to remove the language about causality from the records for those cases.

116. Documents in company files also reveal that in November 1994, Johnson & Johnson received a letter from Dr. Samuel Epstein, chairman of the group known as the Cancer Prevention Coalition (P-18), notifying the CEO of Johnson & Johnson of the filing of the Citizens’ Petition. In that letter, Dr. Epstein requested that talc products be withdrawn from the market due to the concern with human cancer, or that, at least, a label warning should be required for consumers regarding the concerns of ovarian cancer with talc use. Fifteen years later, in 2009, the PCPC filed comments on behalf of industry to this 1994 Citizen’s Petition; the same group filed a

second Citizen's Petition in 2008 because of developing science in the area and the fact that FDA had failed to respond to the original petition filed in 1994. Although industry disagreed with Dr. Epstein's position, it agreed that reasonable scientists looking at the data could disagree with industry, that this disagreement was one that was expressed by responsible scientists over decades, and that defendants could voluntarily change the label without being required to do so by the FDA. Yet, Johnson & Johnson did not warn about the risk of cancer following receipt of their letter in 1994. Given the expertise of Dr. Epstein and the fact that he was pointing to reliable scientific information to support his concerns, Johnson & Johnson had a duty to inform consumers of the potential risks associated with talc use, particularly in women using body powders for genital application.

117. Other industry actions related to talc and the safe use of talc powders in humans that inform my opinions and warrant discussion include the removal of talc powder as a lubricant for condoms and for surgical gloves. With respect to use of talc powder on condoms, manufacturers decided in 1996 to no longer use talc on condoms (IMERYS-A_0011817; 16 January 1996 article in Asbury Park Press; P-0019). The decision was driven in part by the opinions expressed by scientists in the published literature concerning the health hazards associated with talc (Kang *et al.* 1992; Kasper and Chandler, 1995). Talc industry members such as Johnson & Johnson, Imerys and the PCPC were aware of these actions (PCPC_MDL00062175; PCPC0075758). With respect to use of talc powders on surgical gloves, the risks to human health had been recognized in the 1950's (discussed above). In 2016, FDA acted to formally ban use of powders, including talc, on surgical gloves (*Federal Register* December 16, 2016).⁷⁰

118. Documents show that, instead of providing consumers with warnings and safety information regarding use of talcum powder products, industry performed marketing research (*e.g.*, PCPC0077761-77926; P-24). From the results of the market research, industry knew that consumers were unaware of the safety concerns associated with use of talc-based body powders in the genital area. Importantly, during the process of collecting the consumer data, consumers

⁷⁰ It is important to realize that the group at FDA that banned the use in 2016 was the FDA's Center for Devices and Radiological Health (CDRH) which had very different regulatory authority at the time in 2016 (<https://www.govinfo.gov/content/pkg/FR-1998-02-02/pdf/98-2498.pdf>) as compared to the Office of Cosmetics within the FDA's Center for Food Safety and Nutrition (CFSAN).

participating were told that the information on the link of talc use with cancer was “hypothetical”, even though industry was aware of a wide variety of scientific data where well-respected scientists had concluded that talc posed a cancer hazard to humans. Evidence shows industry also marketed talcum body powders by targeting populations with a known propensity to use talc body powders in the genital area (P-10; P-0374; P-771).

119. Documents show that Defendants recognized the health hazard of talcum powder products and the potential consequences of failing to inform the scientific and medical community, regulators, and consumers of those hazards (P-26; P-27; P-66). They even developed a document discussing questioning around the safety issue. The document shows that industry understood that data existed supporting the safety concerns.

IX. Conclusions

120. In conclusion, based on my training and experience in pharmacology, toxicology, pharmacokinetics, human health risk assessment, and the regulation of cosmetic products in the United States, it is my opinion to a reasonable degree of scientific certainty that the weight-of-the-evidence indicates that genital exposure to talcum powder products increases the risk of ovarian cancer in women. This conclusion is supported by data that includes, but is not limited to the following: (1) the known toxic effects of talc and the other components of talcum powder products; (2) studies that have identified biologically plausible mechanisms for cancer in humans; (3) the likelihood that talc particles can reach the ovaries; (4) the existence of a dose-response relationship for toxicity including the risk of cancer; and (5) the large human database that includes studies conducted over a period of 40 years showing a consistent signal for ovarian cancer in women exposed to talcum powder products.

121. It is also my opinion to a reasonable degree of scientific certainty that the use of talc in cosmetic products does not meet the CIR standard of safety. Given the presence of asbestos, fibrous talc, cobalt, chromium, and nickel, in the talc body powders manufactured by Imerys and Johnson & Johnson, a significant biologically plausible human health risk was identified as a hazard related to talc body powder use at least by the 1940's. These risks included a risk of cancer with exposure to constituents of talc body powders, and even death with acute inhalation of large

amounts of the powder. Based on the knowledge available by the 1950's, talc body powders manufactured and sold by Imerys and Johnson & Johnson should have warned consumers about the toxic constituents, such as asbestos, fibrous talc, nickel, chromium and cobalt and fragrance, in their products and the effects that could be produced by exposure to talc dusts. There was evidence from at least the 1960's of the risk of ovarian cancer in women exposed to components of talc body powders, evidence that has only gained strength over the last six decades. The CIR standard states that there is "*no evidence*" that demonstrates grounds to suspect a hazard to the public under conditions of use. Failure to meet the CIR standard for safety meant that Johnson & Johnson failed to properly substantiate and ensure the safety of their cosmetic body powder products. Given that Johnson & Johnson was aware that cornstarch-based body powder products represented a safer alternative, their failure to replace talc with cornstarch over the years that they marketed talc-based body powders put consumer health at risk.

122. Based upon my review of the scientific evidence, it also is my opinion within a reasonable degree of scientific certainty that talc-based cosmetic products, including products used by women for genital dusting, should have been labeled to warn of the risk of ovarian cancer with such use. This specific ovarian cancer risk was evident by the 1960's given the presence of asbestos in talc body powders. This opinion is based on the FDA regulations that state that "*the label of a cosmetic product shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product*" (21 CFR 740.1(a)). It is important to note that cause and effect do not have to be proven for such a warning to be put into place. Given that Defendants have never placed an adequate warning onto its containers of talcum powder products, the failure to provide consumers with such information puts public health at risk.

123. In addition to failing to warn consumers about the serious health risks that had been linked to genital use of talc, where evidence had been accumulating for decades, the presence of carcinogenic constituents in talc such as asbestos, fibrous talc, nickel, chromium, and cobalt meant that Johnson & Johnson's failure to list those talc constituents on its labeling was consistent with the FDA's definition of a misbranded product, and also consistent with the FDA's definition of an adulterated product.

124. Finally, it is my opinion to a reasonable degree of scientific certainty that rather than perform studies to address talc safety concerns that arose over the years, or provide consumers with complete and timely safety information about the human health risks of talc when it was used for genital dusting, industry worked together with the PCPC to influence the scientific and regulatory processes related to cosmetic talcum powder products such that the scientific and medical communities, as well as consumers, were not provided with important safety information about use of the products.

125. I hereby certify that this report is a complete and accurate statement of all my opinions, and the basis and reasons for them, to which I will testify under oath.

X. Compensation

126. My compensation for litigation work, for both defense attorneys and plaintiff attorneys, is at the rate of \$300.00 per hour.

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APPENDIX A
Curriculum Vita

CURRICULUM VITAE

Laura M. Plunkett, Ph.D., D.A.B.T

ADDRESS 1127 Eldridge Pkwy, Suite 300335
Houston, TX 77077

EDUCATION

1984	Ph.D.	Pharmacology	University of Georgia
1980	B.S.	Zoology	University of Georgia

PROFESSIONAL EXPERIENCE

Registered Patent Agent Licata & Tyrrell, P.C., Marlton, N.J., 1999 – present
Assists clients with obtaining patent protection, specializing in products used in medical applications (drugs, devices, dietary supplements). Assists clients with developing regulatory strategies for commercialization of their inventions. Provides regulatory support for companies engaged in manufacturing and marketing of products regulated by the U.S. Food and Drug Administration, the U.S. Environmental Protection Agency and other regulatory bodies in the U.S. and worldwide.

Partner. BioPolicy Solutions LLC, June 2020 – present
Consultant to a variety of clients in areas of pharmacology, toxicology, risk assessment and regulatory strategy. Focus on products regulated by the U.S. Food and Drug Administration. Provides litigation support services as both consulting expert and testifying expert.

President. Integrative Biostrategies (IB) LLC, 2001- May 2020
Consultant to a variety of clients in areas of pharmacology, toxicology, risk assessment and regulatory strategy. Focus on products regulated by the U.S. Food and Drug Administration. Provides litigation support services as both consulting expert and testifying expert.

Owner. Plunkett & Associates, Houston, Texas, 1997 – 2001
Consultant to a variety of clients in areas of pharmacology, toxicology, risk assessment and regulatory strategy. Focus on products regulated by the U.S. Food and

Drug Administration. Provided litigation support services as both consulting expert and testifying expert.

Manager. ENVIRON Corporation, Houston, Texas, 1992 – 1997

Consultant to a variety of clients in areas of pharmacology, toxicology, risk assessment and regulatory strategy. Focus on products regulated by the U.S. Food and Drug Administration. Provided litigation support services as both consulting expert and testifying expert.

Manager. ENVIRON Corporation, Arlington, Virginia, 1989 – 1992

Consultant to a variety of clients in areas of pharmacology, toxicology, risk assessment and regulatory strategy. Focus on products regulated by the U.S. Food and Drug administration.

Assistant Professor. University of Arkansas for Medical Sciences, Department of Pharmacology and Toxicology, 1986 – 1989

Taught medical and graduate student courses in pharmacology (lecture and laboratory), neurosciences, cardiovascular pharmacology, and neuropharmacology. Performed basic research in area of autonomic control of cardiovascular function and neurochemical systems involved in autonomic function. Recipient of extramural funding from the Arkansas Heart Association (principal investigator).

Postdoctoral fellow. National Institute of General Medical Sciences, Pharmacology Research Associate Training Program, 1984 – 1986

Performed basic research in area of neurochemical control of cardiovascular function and neurochemical systems involved in autonomic function.

Research Assistant. University of Georgia, College of Pharmacy, Department of Pharmacology and Toxicology 1980 – 1984

Taught laboratory courses in pharmacology to pharmacy students as part of graduate student assistantship responsibilities.

HONORS AND AWARDS

Chosen for PRAT program at National Institutes of Health. Pharmacology Research Associate Training Program, 1984-1986.

Rho Chi. The University of Georgia, College of Pharmacy, Initiated, 1984.

Recipient of Excellence in Graduate Research Award. The University of Georgia, College of Pharmacy, 1983.

Alpha Lambda Delta. The University of Georgia Chapter, 1978.

PROFESSIONAL CERTIFICATION

Registered patent agent, 1999 [Registration No. 45,015]
Diplomate, American Board of Toxicology, 1993 to present.

ACADEMIC AFFILIATION

Adjunct Professor. Baylor University, Department of Environmental Science, 2017-present

PROFESSIONAL MEMBERSHIPS

Member, Society of Toxicology 1992 – present

President, Society of Toxicology Risk Assessment Specialty Section (RASS) 2021-2022

Vice-President, Society of Toxicology Risk Assessment Specialty Section (RASS) 2020-2021

Vice-President Elect, Society of Toxicology Risk Assessment Specialty Section (RASS) 2019-2020

Member, Lone Star Chapter Society of Toxicology 2007 – present

Councilor, Lone Star Chapter Society of Toxicology 2010 - 2013

Secretary, Lone Star Chapter Society of Toxicology 2013 – 2015

Vice President, Lone Star Chapter Society of Toxicology 2015-2016

President, Lone Star Chapter, Society of Toxicology 2016-2017

Past President, Lone Star Chapter, Society of Toxicology 2017-2018

Member, American College of Toxicology, 1997 - present

Member, Society for Risk Analysis, 2007- present

President, Lone Star Chapter of the Society for Risk Analysis, 1998

Councilor, Lone Star Chapter of the Society for Risk Analysis, 1999-2000

Member, Regulatory Affairs Professionals Society, 2003 - present

Member, Society for Neuroscience 1985 - present

Member, American Association for Pharmaceutical Sciences 1992 – present

Member, Society for Environmental Geochemistry and Health 1992 - present

Member, ASTM Committee E06, 1990 – present

Member, International Association of Plumbing and Mechanical Officials (IAPMO)
Committee Z1123 (Prop 65) Committee, 2020 - present

PUBLICATIONS

1. Bobst, S, Ryan, K, **Plunkett, LM**, Willett, KL. 2020. ToxPoint: Toxicology studies on Δ^9 -tetrahydrocannabinol and cannabidiol-containing products available to consumers are lacking. *Toxicol. Sci.* 178:1-2.
2. Rajendran, N, Seagrave, JC, **Plunkett, LM**, MacGregor, JA. A comparative assessment of the acute inhalation toxicity of vanadium compounds. *Inhal. Toxicol.* 2016. 28:618-628.
3. Cox, LA, Popken, DA, Kaplan, AM, **Plunkett, LM**, Becker, RA. How well can in vitro data predict in vivo effects of chemicals? Rodent carcinogenicity as a case study. *Regul. Toxicol. Pharmacol.* 2016. 77:54-64.
4. **Plunkett, LM**, Kaplan, AM, Becker, RA. Challenges in using the ToxRefDB as a resource for toxicity modeling. *Regul. Toxicol Pharmacol.* 2015. 72:610-614.
5. **Plunkett, LM**, Becker, RA, Kaplan, M. An enhanced tiered toxicity testing framework with triggers for assessing hazards and risks of commodity chemicals. *Regul. Toxicol. Pharmacol.* 2010. 58:382-394.
6. Chambers, A, Krewski, D, Birkett, N, **Plunkett, L**, Hertzberg, R, Danzeisen, R, Aggett, PJ, Starr, TB, Baker, S, Dourson, M, Jones, P, Keen, CL, Meek, B, Schoeny, R, and Slob, W J. An exposure-response curve for copper excess and deficiency.

Toxicol. Environ. Health. 2010. 13:546- 578.

7. Krewski, D, Chambers, A, Stern, BA, Aggett, PA, **Plunkett, L**, Rudenko, L. Development of a copper database for exposure-response analysis. *J. Toxicol. Environ. Health.* 2010. 73:208-216.
8. **Plunkett, LM**, Becker, RA. Does the standard toxicological testing paradigm for industrial chemicals apply to screening for children's health risks? *The Open Toxicol. J.* 2008, 2:42-60.
9. Becker, RA, **Plunkett, LM**, Borzelleca, JF, Kaplan, AM. Tiered toxicity testing: Evaluation of toxicity-based decision triggers for human health hazard characterization. *Food Chem. Toxicol.* 2007, 45:2454-2469.
10. MacGregor, JA, **Plunkett, LM**, Youngren, SH, Manley, A, Plunkett, JB, Starr, TB. Humans Appear No More Sensitive than Laboratory Animals to the Inhibition of Red Blood Cell Cholinesterase by Dichlorvos (DDVP). *Regul. Toxicol. Pharmacol.*, 2005, 43:150-167.
11. **Plunkett, LM**. Do current FIFRA guideline tests protect infants and children? Lead as a case study. *J Regul Toxicol Pharmacol* 1999;29:80-87.
12. **Plunkett, LM**, Seifen E, Kennedy RH. Effect of morphine pretreatment on cocaine cardiotoxicity in anesthetized guinea pigs. *Arch Int Pharmacodyn* 1989;297:60-67.
13. Zorbas M., Owens SM, **Plunkett LM**, Bui H. The pharmacokinetics of [3H]-[1-(2-thienyl)cyclohexyl]piperidine (TCP) in Sprague Dawley rats. *J Drug Metab Disposit* 1989;17:641-645.
14. Seifen E, **Plunkett LM**, Kennedy RH. Cardiovascular and lethal effects of cocaine in anesthetized dogs and guinea pigs. *Arch Int Pharmacodyn* 1989;300:241-253.
15. McCarty R, **Plunkett LM**. Regulation of binding sites for atrial natriuretic factor (ANF) in rat brain. *Peptides* 1988;9(S1):3-8.
16. Stewart RE, Swithers SE, **Plunkett LM**, McCarty R. ANF receptors: distribution and regulation in central and peripheral tissues. *Neurosci Biobehav Rev* 1988;12:151-168.
17. **Plunkett LM**, Tackett RL. Central dopamine receptors and their role in digoxin-induced cardiotoxicity in the dog. *J Pharm Pharmacol* 1987;39:29-34.
18. **Plunkett LM**, Tackett RL. Increases in CSF norepinephrine associated with the

onset of cardiac glycoside toxicity. *Eur J Pharmacol* 1987;136:119-122.

19. McCarty R, **Plunkett LM**. Quantitative autoradiographic analysis of somatostatin binding sites in discrete areas of rat brain. *Brain Res Bull* 1987;18:289-94.
20. **Plunkett LM**, Shigematsu K, Kurihara M, Saavedra JM. Localization of angiotensin II receptors along the anteroventral-third ventricle area of the rat brain. *Brain Res* 1987;405:205-212.
21. Israel A, **Plunkett LM**, Saavedra JM. Increased number of angiotensin II binding sites determined by autoradiography in anterior pituitary of water deprived and Brattleboro rats. *Neuroendocrinol* 1986;42:57-63.
22. Saavedra JM, Correa FMA, **Plunkett LM**, Israel A, Kurihara M, Shigematsu K. Angiotensin and atrial natriuretic peptide binding in brain of hypertensive rats. *Nature* 1986;320:758-760.
23. McCarty RM, **Plunkett LM**. Forebrain atriopeptin binding sites: Alterations in spontaneously hypertensive rats. *Neurochem Int* 1986;9:177-183.
24. Shigematsu K, Saavedra JM, **Plunkett LM**, Kurihara M, Correa FMA. Angiotensin II binding sites in the anteroventral-third-ventricle (AV3V) area and related structures of the rat brain. *Neurosci Lett* 1986 67:37-41.
25. Correa FMA, **Plunkett LM**, Saavedra JM. Quantitative distribution of angiotensin-converting enzyme (kininase II) in discrete areas of the rat brain by autoradiography with computerized microdensitometry. *Brain Res* 1986;275:259-266.
26. Saavedra JM, Israel A, **Plunkett LM**, Kurihara M, Shigematsu K, Correa FMA. Quantitative distribution of angiotensin II binding sites in rat brain by autoradiography. *Peptides* 1986;7:679-687.
27. McCarty R, **Plunkett LM**. Binding sites for atrial natriuretic factor (ANF) in brain: alterations in Brattleboro rats. *Brain Res Bull* 1986;17:767-772.
28. **Plunkett LM**, Gokhale RD, Vallner JJ, Tackett RL. Prazosin alters free and total plasma digoxin in dogs. *Am Heart J* 1985;109:847-851.
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receptors in rat anterior pituitary. *Am J Physiol* 1985;248 (Endocrino. Metabl. II):E264-E267.

31. Niwa M, Shigematsu K, **Plunkett L**, Saavedra JM. High affinity substance P binding sites in rat sympathetic ganglia. *Am J Physiol* 1985;249 (Heart Circ. Physiol 18):H694-H697.
32. Correa FMA, **Plunkett LM**, Saavedra JM, Hichens M. Quantitative autoradiographic determination of angiotensin-converting enzyme (kininase II) kinetics in individual rat brain nuclei with 125I-351A, a specific enzyme inhibitor. *Brain Res* 1985;347:192-195.
33. Israel A, Niwa M, **Plunkett LM**, Saavedra JM. High affinity angiotensin receptors in rat adrenal medulla. *Regul Pept* 1985;11:237-243.
34. Israel A, **Plunkett LM**, Saavedra JM. Quantitative autoradiographic characterization of receptors for angiotensin II and other neuropeptides in individual brain nuclei and peripheral tissues from single rats. *Cell Mol Neurobiol* 1985;5:211-222.
35. **Plunkett LM**, Correa FMA, Saavedra JM. Quantitative autoradiographic determination of angiotensin-converting enzyme kinetics in rat pituitary and adrenal glands with 125I-135A, a specific inhibitor. *Regul Pept* 1985;12:1-10.
36. **Plunkett LM**, Saavedra JM. Increased angiotensin II binding affinity in the nucleus tractus solitarius of spontaneously hypertensive rats. *Proc Natl Acad Sci* 1985;82:7721-7724.
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ABSTRACTS

1. Woodall, G.M., Grimm, F.A, Pechacek, N., Wignall, J., Minsavage, G.D. and **Plunkett, L.M.** Risk Assessment Syllabus. Society of Toxicology annual meeting, March 19-23, 2023, Nashville, TN.
2. **Plunkett, L.M.** Cannabidiol Incorporation into Consumer Products in the US: Regulatory Challenges to Commercialization. Presenting at the Society of Toxicology annual meeting. March 25, 2021. Virtual Meeting.
3. **Plunkett, LM.** Cannabidiol Incorporation into Consumer Products in the US:

Regulatory Challenges to Commercialization. Presenting at the annual meeting of the American Association for the Advancement of Science (AAAS), February 8-11, 2021. Virtual meeting

4. **Plunkett, LM.** Marijuana and Public Safety Concerns: States in Charge. Presenting at Society of Toxicology annual meeting. March 11-15, 2018, San Antonio, Texas.
5. Cox, LA, Popken, DA, Kaplan, AM, **Plunkett, LM**, Becker, RA. How well do High Throughput Screening (HTS) assay data predict in vivo rodent carcinogenicity of pesticides? Presenting at Society for Risk Analysis annual meeting, December 11-15, 2016, San Diego, California.
6. **Plunkett, LM.** THC and legal issues related to the state of the science. Symposium presenter at the Society of Toxicology, New Orleans, LA, March 2016.
7. Goyak, K, Alyea, R, Becker, RA, **Plunkett, LM**, Plunkett, JB. Evaluating the ability of high-throughput screening (HTS) assays to capture the biological activity of industrial chemicals. Poster presentation at the Society of Toxicology, New Orleans, LA, March 2016.
8. MacGregor, JA, Plunkett, JB, **Plunkett, LM.** The occurrence of chemically induced lung tumors in rodents as an outcome in NTP chronic bioassays and the impact on cancer classifications. Presented at the Society of Toxicology, San Diego, CA, March 2015.
9. Urban, JD, Thompson, CM, **Plunkett, LM**, Perry, C, Haws, LC. A state of the science of copper reference dose for soil remediation. Presented at the Society of Toxicology, San Diego, CA, March 2015.
10. **Plunkett, LM**, Kaplan, AM, Becker, RA. Evaluation of a tiered toxicity testing decision trigger for assessing reproductive hazards of commodity chemicals. Submitted for presentation at the Society of Toxicology, Phoenix, AZ, March 2014.
11. **Plunkett, L.M.** Overview of key public and worker health concerns in Texas food production. Presented at the Society of Toxicology, San Antonio, TX, March 2012.
12. **Plunkett, L.M.**, Starr, T.B., MacGregor, J.A., Manley, A. Corn oil as a causative factor for proliferative lesions of the forestomach in B6C3F1 mice exposed by gavage. Presented at Society of Toxicology, Washington, D.C., March 9, 2011. [Award received for "Best Presentation"]
13. **Plunkett, LM**, MacGregor, JA, Starr, TB, Manley, A. Daily gavage with corn oil is a causative factor for proliferative lesions of the forestomach in B6C3F1 mice.

Toxicology Lett. 189S:S142. Presented at EUROTOX, Dresden, Germany, September 14, 2009.

14. **Plunkett, LM**, MacGregor, JA, Starr, TB, Youngren, SH, Manley, A. Determination of a dichlorvos-specific acute interspecies uncertainty factor. Society of Toxicology, Seattle, WA, March 19, 2008.
15. **Plunkett, LM**, Starr, TB, Youngren, SH, MacGregor, JA, Manley, A. Determination of the magnitude of intraspecies differences in red blood cell cholinesterase inhibition in response to dichlorvos exposure. Society of Toxicology, San Diego, CA, March 6, 2006.
16. **Plunkett, LM**, Licata, JM. What every technology manager needs to know about FDA law. Association of University Technology Managers (AUTM), Orlando, FL, March 4, 2006.
17. **Plunkett, LM**, Licata JM. What every technology manager needs to know about FDA law. Association of University Technology Managers (AUTM), Phoenix, AZ February 2005.
18. **Plunkett, LM**. Qualitative Interpretation of Complex and Disparate Data Sets for Dose-Response Assessment of Essential Trace Elements: Copper as a Case Study. Society for Toxicology, Baltimore, MD March 2004 .
19. **Plunkett, LM**. Evaluating qualitative and quantitative dose-response data in complete data sets for comparative dose-response assessment. Soc. Risk Analysis, Baltimore, MD, December 10, 2003.
20. **Plunkett, LM**, Rieth S, Starr T. Issues in assessing risks for cholinesterase-inhibiting pesticides: A decision tree approach. Soc. Risk Analysis, New Orleans, LA, December 9-12, 1996
21. **Plunkett, LM**, Brown S. Assessment of the potential neuropathic risk to banana workers from dermal exposure to chlorpyrifos. Soc. Risk Analysis, Honolulu, HI, December 3-7, 1995

22. **Plunkett, LM**, Russell K. Cooperation versus Confrontation: Reconciling Lead regulations, exposure studies, and public perception. SEGH Conference, July, Salt Lake City, UT, 1994
23. **Plunkett LM**, Wixtrom RN, Cabrera CR. Evaluation of the long-term safety of inflatable penile prostheses: a critical analysis of potential carcinogenic, reproductive, teratogenic, or adverse immunological effects of silicone. Western Section of American Urological Association Meeting, Seattle, WA, August 21-25, 1994
24. Wixtrom RN, **Plunkett LM**, Clarkin CM. Complications of inflatable penile prostheses: A comprehensive review of infection, mechanical complications, erosion/migration/extrusion, and fibrous capsule formation. 1994.
25. Wixtrom RN, Clarkin CM, Purkait B, **Plunkett LM**. A review of clinical experience with the Mentor Alpha I and Mark II inflatable penile prostheses. 1994.
26. **Plunkett LM**, Rosolowsky LJ, Lerner DM, Washburn ST. A biokinetic model for predicting blood lead levels in adults living near a former battery recycling facility. SEGH Conference, New Orleans, LA, July, 1993.
27. Rosolowsky LJ, Edelmann KG, **Plunkett LM**. A biokinetic model for predicting blood lead levels in adults that accounts for intermittent exposures. Society for Risk Analysis, December, 1993
28. **Plunkett LM**, Owens SM, Gunnell M, Owens RB. The effect of chronic phencyclidine (PCP) and phenylcyclohexene (PC) dosing on [3H]TCP and [3H] haloperidol binding in rat brain. *FASEB J* 1990;4:A329.
29. Owens RB, Owens SM, Gunnell M, **Plunkett LM**. 1990. The effect of chronic phencyclidine (PCP) and phenylcyclohexene (PC) on lymphocyte in subsets in rats. *FASEB J* 1990;4:A337.
30. Zorbas M, Owens SM, **Plunkett LM**, Bui H. [3H]TCP protein binding and pharmacokinetics in Sprague-Dawley rat. *FASEB J* 1989;3:A1036.
31. **Plunkett LM**, Kennedy RH, Seifen E. Effects of chronic stress on myocardial beta-adrenergic receptor binding. *The Pharmacologist* 1988;A1300.

32. Evans, R.E., **Plunkett LM**, Kennedy RH, Seifen E. [3H]Ouabain binding to regions of rat heart as determined by autoradiography. *The Pharmacologist* 1988;A41.
33. Massey BW, **Plunkett LM**, Kennedy RH, Seifen E. Alterations in brain angiotensin II binding in the aged rat. Soc. Neuroscience 1987 Abstracts, p. 722.
34. **Plunkett LM**, Alexander N, Saavedra JM. Altered angiotensin II binding in adrenal gland, pituitary gland and brain of sinoaortic denervated rats. Am. Soc. Hypertension. New York, NY, May 1986.
35. Saavedra JM, **Plunkett LM**, Correa FMA. Increased number of angiotensin II binding sites in the subfornical organ of spontaneously hypertensive rates. Am. Soc. Hypertension, New York, NY, May 1986.
36. **Plunkett LM**, Niwa M, Shigematsu K, Saavedra JM. Increased angiotensin II (ANG) binding in superior cervical ganglia of spontaneously hypertensive rats (SHR). *Fed. Proc* 1985;3: 498.
37. **Plunkett LM**, Saavedra JM. Discrete localization of angiotensin II (ANG) binding sites in rat brainstem by quantitative autoradiography. Neural and Endocrine Peptides and Receptors, Symposium, Washington, D.C., May, 1985.
38. **Plunkett LM**, Israel A, Niwa M, Shigematsu K, Saavedra JM. Alterations in angiotensin II binding in pituitary gland, adrenal gland and superior cervical ganglia of spontaneously hypertensive rats (SHR) as determined by quantitative autoradiography. Neural and Endocrine Peptides and Receptors, Symposium, Washington, DC, May 1985.
39. Shigematsu K, Niwa M, **Plunkett LM**, Saavedra JM. High affinity substance P binding sites in rat sympathetic ganglia. Neural and Endocrine Peptide and Receptors, Symposium '85, Washington, DC, May 1985.
40. McCarty R, **Plunkett LM**, Israel A, Saavedra JM. Quantitation of somatostatin binding sites in rat brain. Neural and Endocrine Peptides and Receptors, Symposium '85, Washington, DC, May, 1985.

41. **Plunkett LM**, Saavedra JM. Increased angiotensin II (ANG) binding in brainstem nuclei of adult spontaneously hypertensive rats (SHR) by quantitative autoradiography. Interamerican Society of Hypertension, Cleveland, OH, May 1985.
42. Saavedra JM, **Plunkett LM**, Niwa M, Israel A, Shigematsu K, R. McCarty, Correa FMA. Autoradiographic-microdensitometric methods for the kinetic analysis of neuropeptide receptors and peptidases in individual brain nuclei. IVth World Congress of Biological Psychiatry, Philadelphia, PA, September, 1985.
43. **Plunkett LM** Saavedra JM. 1985. Altered angiotensin II binding in ganglia and brainstem nuclei of spontaneously hypertensive rats (SHR). Council for High Blood Pressure Research, Cleveland, OH, September 1985.
44. **Plunkett LM**, Correa FMA, Saavedra JM. Quantification of angiotensin-1-converting enzyme kinetics in individual rat pituitary and adrenal glands with 125I-MK351A, a specific enzyme inhibitor. Society for Neuroscience, Dallas, Texas, October 1985.
45. McCarty R, **Plunkett LM**, Shigematsu K, Saavedra JM. Quantitative autoradiographic analysis of somatostatin binding sites in discrete areas of rat brain. Society for Neuroscience, Dallas, Texas, October, 1985.
46. Correa FMA, **Plunkett LM**, Saavedra JM. Quantitative autoradiographic determination of angiotensin-converting enzyme distribution in rat brain with 125I-MK351A, a specific inhibitor. Society for Neuroscience, Dallas, Texas, October 1985.
47. **Plunkett LM**, Saavedra JM. Altered angiotensin II binding kinetics in brainstem, pituitary gland, and adrenal gland in adult SHR. 5th International Symposium on SHR and Related Studies, Tokyo, Japan, October, 1985.
48. **Plunkett LM**, Tackett RL. CSF catecholamine activity decreases during cardiac glycoside-induced arrhythmogenesis. *The Pharmacologist* 1985; 25:745.
49. Tackett RL, **Plunkett LM**. Naloxone inhibits the central hypotensive actions of propranolol. *The Pharmacologist* 1983;25:101.

50. **Plunkett LM**, Vallner JJ, Tackett RL. Prazosin lowers plasma digoxin levels. American Heart Assoc, pp 15, Savannah, GA, 1983.
51. Tackett RL, **Plunkett LM**. 1983. BHT 933 lowers blood pressure and increases cerebrospinal fluid norepinephrine levels. American Heart Assoc, pp 16, Savannah GA, 1983.
52. Bayoumi SM, Gokhale R, **Plunkett L**, Vallner JJ. Pharmacokinetics of clortrimazole in dogs. *Acad. Pharmaceut. Sci* 1983;13(2):204, (Miami meeting).
53. **Plunkett LM**, Tackett RL. Central alpha receptors and their role in digitalis cardiotoxicity. *The Pharmacologist* 1982; 24:489A.
54. **Plunkett LM**, Tackett RL. Central alpha antagonism decreases blood pressure in the dog. *Proc. Soc. Exp. Biol. Med. S.E. Sec.* 7:12A 1982.

PRESENTATIONS

1. **Plunkett, LM**. Reproductive Toxicology. Invited lecture at NYU, Department of Environmental Medicine. October 28, 2020.
2. **Plunkett, L.M.** Provided public comments at the FDA-sponsored public meeting on “Testing Methods for Asbestos in Talc and Cosmetic Products Containing Talc”, February 4, 2020.
3. **Plunkett, L.M.** Pesticide Toxicology. Invited lecture at NYU, Department of Environmental Medicine. December 4, 2019.
4. **Plunkett, L.M.** Practical applications of risk assessment. Lecturer at University of Texas Medical Branch at Galveston, Department of Pharmacology and Toxicology. October 19, 2018.
5. **Plunkett, LM**. Non-obviousness and §103. Lecturer at Rutgers School of Law, Camden Campus. November 6, 2012.

6. **Plunkett, LM.** Regulatory primer for pharmacy students: focus on human therapeutics. Invited speaker for the AAPS Visiting Scientist Program, Texas A&M University, College of Pharmacy, Kingsville, TX, May 1, 2009.
7. **Plunkett, LM.** Strategies for reducing adverse drug reactions: Science versus regulatory considerations. Invited speaker for the AAPS Visiting Scientist Program, Texas A&M University, College of Pharmacy, Kingsville, TX, May 1, 2009.
8. **Plunkett, LM.** Novelty requirement of §102. Lecturer at Drexel University School of Law. September 22 and 24, 2008.
9. **Plunkett, LM.** Novelty requirement of §102. Lecturer at Rutgers School of Law, Camden Campus. September 22 and 24, 2008.
10. **Plunkett, LM.** Discussion of the Adequacy of Current Regulatory Risk Assessment Approaches for Protection of Children's Health and the Health of Other "Sensitive" Human Subpopulations. Testimony before the U.S. Senate Environment and Public Works Committee. April, 29, 2008.
11. **Plunkett, LM.** Strategies for reducing adverse drug reactions: Science versus regulatory considerations. Invited speaker for the AAPS Visiting Scientist Program, Florida A&M University, Tallahassee, FL, October 26, 2006.
12. **Plunkett, LM.** The guidance as currently implemented: experience with Minnesota's draft risk levels. Presented at the ISRTP workshop entitled: EPA's New (Proposed) Guidance for Assessing Cancer Risks from Early Life Exposures. Genotoxic Mode of Action and Implications for Human Health-Based Standards. Baltimore, MD February 10, 2005.
13. **Plunkett, LM.** An overview of the regulation of products of biotechnology: Who's in charge? Lecturer at University of Houston at Clearlake, November 17, 2004.
14. **Plunkett, LM.** Moderator of the symposium entitled "Regulation of genetically modified cells, foods, organisms and animals for consumer and therapeutic use. Meeting of the American Association of Pharmaceutical Sciences (AAPS), Baltimore, MD, November 11, 2004.

15. **Plunkett, LM.** A Road map to the US Food And Drug Administration Regulations. Invited Speaker and Session Co-chair, Federation of European Biochemical Societies (FEBS), Istanbul, Turkey, October 20-24, 2002.
16. **Plunkett, LM.** An overview of the regulation of products of biotechnology: Who's in charge? Lecturer at University of Houston at Clearlake, November 2001.
17. **Plunkett, LM.** Differences and Similarities Between Children and Adults in their Exposure and Response to Environmental Chemicals: An Update Since 1992. Invited Speaker at ToxForum, Aspen CO, July 2001.
18. **Plunkett, LM.** Do current FIFRA guideline tests protect infants and children? Lead as a case study. Invited speaker at the Sixteenth International Neurotoxicology Conference, Pesticides and Susceptible Populations: Who is at Risk and When? Little Rock, Arkansas, September 13-16 1998
19. **Plunkett, LM.** An overview of biotechnology regulations: the USFDA and the USEPA. Lecturer at University of Houston at Clearlake, October 16 1998.
20. Rodricks, JV, Santamaria, AB, **Plunkett, LM.** Risk Assessment as a Tool in Litigation: A Discussion of the Uses and Their Limits [Presented by **Plunkett LM**]. Society for Risk Analysis, , New Orleans, LA. December 10 1996.
21. **Plunkett, LM.** Current Issues in Lead Exposure and Risk Assessment. Symposia at the annual meeting of The American College of Toxicology, Valley Forge, PA. November 9 1996.
22. **Plunkett, LM.** An Overview of Biotechnology Regulations: Environmental Regulations. Lecturer at the South Texas School of Law, October 1995.
23. **Plunkett, LM.** An Overview of Biotechnology Regulations: FDA Regulations. Lecturer at the South Texas School of Law, October 1995.
24. **Plunkett, LM.** A Discussion of Toxicokinetics. Featured speaker at a symposium at the Int. Congress of Toxicol., July 5 1995.
25. **Plunkett, LM.** Chutes and Ladders: The Hazardous Journey for R&D to Market. Featured speaker at the Futurist's Conference, Irvine, CA, June 28, 1995.

BOOK CHAPTERS

1. Rudenko, L, **Plunkett, LM**, Kornum, A, Rocklinsberg, H, Sorensen, DB, Gjerris, M. 2024. An overview of the regulation of genetically altered animals in research. In: *Biotech Animals in Research: Ethical and Regulatory Aspects*. CRC Press: Boca Raton. Chapter 3.
2. Anderson, SA, **Plunkett, LM**. 2023. Defending Pesticides in Litigation. Thomson Reuters, Eagan, MN.
3. Anderson, SA, **Plunkett, LM**. 2022. Defending Pesticides in Litigation. Thomson Reuters, Eagan, MN.
4. Anderson, SA, **Plunkett, LM**. 2021. Defending Pesticides in Litigation. Thomson Reuters, Eagan, MN.
5. Anderson, SA, **Plunkett, LM**. 2020. Defending Pesticides in Litigation. Thomson Reuters, Eagan, MN.
6. Anderson, SA, **Plunkett, LM**. 2019. Defending Pesticides in Litigation. Thomson Reuters, Eagan, MN.
7. **Plunkett, LM**, O'Donnell, JT. 2016. Ketorolac abuse and injury in college athletics. In: *O'Donnell's Drug Injury, Fourth Edition*. O'donnell and O'Donnell (eds.), Lawyers & Judges Publishing Company, Inc: Tucson, AZ, pp. 591-602.
8. **Plunkett, LM**, Timmerman, LE. 2011. Pharmacovigilance and Postmarket Surveillance in the United States: The Role of the U.S. Food and Drug Administration. In: *Elements of Pharmacovigilance: Be Vigilant, Be Safe*. R. Sehgal *et al.* (Eds.), Kongposh Publications: New Dehli.
9. Rodricks, JV, Frankos, VH, **Plunkett, LM**. 1995. Food Additives. In: *Regulatory Toxicology*. C.P. Chengelis, J.F. Holson and S.C. Gad (eds.) Raven Press, New York, New York, 51-82.

10. **Plunkett, LM**, Turnbull, D, Rodricks, JV. 1992. Differences between adults and children affecting exposure assessment. In: Similarities and Differences Between Children and Adults: Implications for Risk Assessment. P.S. Guzelian, C.J. Henry and S.S. Olin (eds.) ILSI Press, Washington D.C., 79-96.
11. Saavedra JM, **Plunkett LM**, Correa FMA, Israel A, Kurihara M, Shigematsu K. 1986. Quantitative autoradiography of angiotensin and atrial natriuretic factor binding sites in brain nuclei of spontaneously hypertensive rats. In Brain Peptides and Catecholamines in Cardiovascular Regulation in Normal and Disease States.

MISCELLANEOUS

1. **Plunkett LM**. 2008. U.S. Senate Committee on Environment & Public Works. Oral testimony. Full Committee hearing entitled "Oversight on EPA Toxic Chemical Policies". Tuesday, April 29, 2008.
2. **Plunkett LM**, Brett SM. 1991. A new look at lead: sources, exposures, and uptake in populations at risk. ENVIRON Report. 5:6-9.
3. **Plunkett LM**, Frankos VH. 1991. FDA re-examines the safety of silicone gel-filled breast implants. ENVIRON Report. 5:10-13.

APPENDIX B

Trial List

List of Testimony for Dr. Laura M. Plunkett, Ph.D, DABT

Year	Case Name	Law Firm Represented
2018	<i>Cell Phone Litigation Deposition Testimony November 15, 2018</i>	Lundy, Lundy, Soileau & South (Lake Charles, LA)
2018	<i>Gadolinium Kish v. GE Electric Deposition Testimony 27 November 2018</i>	Power Rogers & Smith, PC
2018	<i>Taxotere Deposition Testimony 10 December 2018</i>	The Lambert Law Firm (New Orleans, LA)
2018	<i>Talc Brower case Georgia Deposition 18 December 2018</i>	Beasley Allen (Montgomery, AL)
2018	<i>Talc MDL Deposition 19 December 2018</i>	Ashcraft & Gerel LLP (Alexandria, VA)
2019	<i>Pradaxa Litigation Supplemental Deposition 07 Janaury 2019</i>	The Nemeroff Firm (Dallas, TX)
2019	<i>Kubicki v. Medtronic, Inc. et al Deposition 06 March 2019</i>	Ashcraft & Gerel LLP (Alexandria, VA)
2019	<i>McCants v. Vitacost, Inc. Trial Testimony 29 March ; 01 April 2019</i>	Miller Weisbrod (Dallas, TX)

Year	Case Name	Law Firm Represented
2019	<i>Daniels-Feasel et al v. Forest Pharmaceuticals, Inc., et al</i> <i>Deposition</i> <i>12 April 2019</i>	Nidel & Nace PLLC (Washington, DC)
2019	<i>Taxotere</i> <i>Deposition</i> <i>22 April 2019</i>	David F. Miceli, LLC (Carrollton, GA)
2019	<i>Pradaxa Litigation</i> <i>Ridings v. BIPI</i> <i>27 April 2019</i>	Humphreys, Farrington & McClain (Independence, MO)
2019	<i>Roberto v. BIPI</i> <i>Trial Testimony</i> <i>1-3 May 2019</i>	Ury, Moskow (Fairfield, CT)
2019	<i>Emley, Donna v. Wal-Mart Stores, Inc., et al.</i> <i>Deposition</i> <i>14 May 2019</i>	Childers, Schlueter & Smith (Atlanta, GA)
2019	<i>Ruiz v. TEVA, et al</i> <i>Deposition</i> <i>10 June 2019</i>	Searcy, Denney, Scarola, Barnhart & Shipley (West Palm Beach, FL)
2019	<i>Pleasant v. Wellington Regional Med Ctr, et al.</i> <i>Deposition</i> <i>02 July 2019</i>	Searcy, Denney, Scarola, Barnhart & Shipley (West Palm Beach, FL)
2019	<i>Thomas, et al. v. Mobil Oil Corp, et al</i> <i>Deposition</i> <i>10 July 2019</i>	Fransen & Hardin, PLC (New Orleans, LA)
2019	<i>Ruiz v. TEVA, et al</i> <i>Deposition (continuation of 10 June deposition)</i> <i>31 July 2019</i>	Searcy, Denney, Scarola, Barnhart & Shipley (West Palm Beach, FL)
2019	<i>Coleman case (Cook Medical)</i> <i>Deposition</i> <i>01 August 2019</i>	Matthews & Associates (Houston, TX)

Year	Case Name	Law Firm Represented
2019	<i>Talc</i> <i>Brower case Georgia (J&J)</i> <i>Trial</i> <i>12-16 September 2019</i>	Beasley, Allen (Montgomery, AL)
2019	<i>Taxotere MDL</i> <i>Trial</i> <i>18 September 2019</i>	David F. Miceli, LLC (Carrollton, GA)
2019	<i>Lilla v. Cordis Corporation</i> <i>Deposition</i> <i>16 October 2019</i>	Freese & Goss (Dallas, TX)
2019	<i>Ridings v. BIPI</i> <i>Hearing</i> <i>28-29 October 2019</i>	Humphreys, Farrington & McClain (Independence, MO)
2019	<i>Lilla v. Cordis Corporation</i> <i>Deposition (CONTINUATION)</i> <i>31 October 2019</i>	Freese & Goss (Dallas, TX)
2019	<i>Seegert, et al. V. Rexall Sundown, Inc.</i> <i>Deposition</i> <i>06 November 2019</i>	Blood Hurst & O'Reardon, LLP (San Diego, CA)
2019	<i>Six v. CSX Corporation</i> <i>Deposition</i> <i>11 November 2019</i>	Franklin Law, LLC (Savannah, GA)
2019	<i>Cadigan v. Johnson & Johnson (Talc)</i> <i>Deposition</i> <i>13 November 2019</i>	Beasley Allen (Montgomery, AL)
2019	<i>Crayton & Thibodeaux case (Taxotere)</i> <i>Deposition</i> <i>19 November 2019</i>	David F. Miceli, LLC (Carrollton, GA)
2019	<i>Lyons v. BIPI (Pradaxa)</i> <i>Deposition</i> <i>25 November 2019</i>	Ury, Moskow (Fairfield, CT)

Year	Case Name	Law Firm Represented
2019	<i>Forrest v. Johnson & Johnson (Talc)</i> <i>Trial Testimony</i> <i>06, 09-10 December 2019</i>	Beasley Allen (Montgomery, AL)
2019	<i>Crayton & Thibodeaux case (Taxotere)</i> <i>Deposition (CONTINUATION)</i> <i>13 December 2019</i>	David F. Miceli, LLC (Carrollton, GA)
2020	<i>McDermitt case</i> <i>Deposition</i> <i>21 January 2020</i>	Goldenberg Law, PLLC (Minneapolis, MN)
2020	<i>Benitez v. Dr. Ronald Seguar</i> <i>Deposition</i> <i>23 January 2020</i>	Orrill & Malbrough, LLC (Metairie, LA)
2020	<i>State of Hawai'i (Clare E. Connors, Attorney General) v. Bristol-Myers Squibb (BMS) et al.</i> <i>Deposition</i> <i>21 February 2020</i>	Baron and Budd (Encino, CA)
2020	<i>Kahn case (Taxotere)</i> <i>Deposition</i> <i>27 April 2020</i>	David F. Miceli, LLC (Carrollton, GA)
2020	<i>Sandra Sutter v. Cordis (IVC)</i> <i>Deposition</i> <i>27 May 2020 and 8 June 2020</i>	Blankenship Law Firm (Dallas, TX)
2020	<i>Roney v. Provient</i> <i>Deposition</i> <i>20 July 2020</i>	Smith, LaCien LLP (Chicago, IL)
2020	<i>Taxotere 505b2 Cases</i> <i>03 & 08 September 2020</i>	David F. Miceli, LLC (Carrollton, GA)
2020	<i>State of Hawai'i (Clare E. Connors, Attorney General) v. Bristol-Myers Squibb (BMS) et al.</i> <i>Trial</i> <i>26-27 October 2020</i>	Baron and Budd (Encino, CA)

Year	Case Name	Law Firm Represented
2021	<i>Kahn case (Taxotere)</i> <i>Deposition</i> <i>7 April 2021</i>	David F. Miceli, LLC (Carrollton, GA)
2021	<i>Cadigan v. Johnson & Johnson (Talc)</i> <i>Trial Testimony</i> <i>14-16 July 2021</i>	Beasley Allen (Montgomery, AL)
2021	<i>Talc MDL</i> <i>Deposition</i> <i>10 August 2021</i>	Ashcraft & Gerel LLP (Alexandria, VA) Beasley Allen (Montgomery, AL)
2021	<i>Kleiner v. Johnson & Johnson (Talc)</i> <i>Trial Testimony</i> <i>18-20 and 23-24 August 2021</i>	Beasley Allen (Montgomery, AL)
2021	<i>Geise et al. v. Johnson & Johnson (Talc)</i> <i>Trial Testimony</i> <i>10, 13-14 September 2021</i>	Beasley Allen (Montgomery, AL)
2021	<i>Guilbault and Plaisance v. 505b2 Defendants</i> <i>Deposition</i> <i>24 September 2021</i>	David F. Miceli, LLC (Carrollton, GA)
2021	<i>Kahn v. Sanofi Aventis</i> <i>Trial Testimony</i> <i>12 November 2021</i>	David F. Miceli, LLC (Carrollton, GA)
2021	<i>State of New Mexico v. Bristol-Myers Squibb</i> <i>(BMS) et al.</i> <i>Deposition</i> <i>19 November 2021</i>	Baron & Budd (Encino, CA)
2021	<i>Mooneyham v. Bactolac</i> <i>9 December 2021</i>	Beasley Allen (Montgomery, AL)
2022	<i>Earnest case (Taxotere)</i> <i>Deposition</i> <i>01 June 2022</i>	David F. Miceli, LLC (Carrollton, GA)

Year	Case Name	Law Firm Represented
2023	<i>Valsartan MDL Deposition 12 January 2023</i>	Levin, Papantonio (Pensacola, FL) Hollis Firm (Kansas City, KS)
2023	<i>Valsartan MDL Deposition (continued) 10 February 2023</i>	Levin, Papantonio (Pensacola, FL) Hollis Firm (Kansas City, KS)
2023	<i>Earnest case (Taxotere) Deposition (Continuation) 28 March 2023</i>	Milberg Coleman (Knoxville, TN)
2023	<i>Norwood v. Albertson's Inc. Deposition 17 May 2023</i>	Lundy. Soileau (Lake Charles, LA)
2023	<i>Jackson v. Bayer HealthCare Pharmaceuticals Inc., et al., 20 July 2023</i>	Yerrid Law (Tampa, FL)
2023	<i>State of Hawai'i (Attorney General) v. Bristol- Myers Squibb (BMS) et al. Deposition 29 August 2023</i>	Baron & Bud (Encino, CA)
2023	<i>State of Hawai'i (Attorney General) v. Bristol- Myers Squibb (BMS) et al. Trial 25, 29 September and 2 October 2023</i>	Baron & Bud (Encino, CA)
2023	<i>Blakely, et al v. Lifecell Deposition 19 October 2023</i>	Cohen Malad (Indianapolis, IN)

Year	Case Name	Law Firm Represented
2023	<i>Mississippi AG v. Johnson & Johnson (Talc)</i> <i>Deposition</i> <i>24 October 2023</i>	Beasley Allen (Montgomery, AL)

APPENDIX C

List of Materials and Data Considered

Documents

C&M-LUZ00013326	IMERYS 026527	IMERYS 032719
CYWM-MA60414-0001	IMERYS 026529	IMERYS 032928
CYWM-MA60523-0001	IMERYS 026536	IMERYS 033027
FDA00003187	IMERYS 026663	IMERYS 033192
FDA00003300	IMERYS 027063	IMERYS 033263
FDA00003326	IMERYS 027080	IMERYS 033295
FDA00003426	IMERYS 027216	IMERYS 033416
FDAFOIA 000001	IMERYS 027349	IMERYS 033423
IMA-NA0000082	IMERYS 027412	IMERYS 033456
IMA-NA0000114	IMERYS 027504	IMERYS 033690
IMA-NA0000232	IMERYS 027596	IMERYS 034215
IMA-NA0000241	IMERYS 027850	IMERYS 034472
IMA-NA0000528	IMERYS 027894	IMERYS 034549
IMA-NA0000532	IMERYS 028080	IMERYS 034569
IMA-NA0000558	IMERYS 028358	IMERYS 034656
IMA-NA0000570	IMERYS 028485	IMERYS 034749
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PCPC0072893	PCPC0075296	PCPC0075782
PCPC0073193	PCPC0075328	PCPC0075812
PCPC0073313	PCPC0075364	PCPC0075827
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APPENDIX D

Chemicals in the Johnson & Johnson Body Powder Fragrance with Irritant Properties

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
(d)-Limonene	Y		<p>https://pubchem.ncbi.nlm.nih.gov/compound/440917#section=Safety-and-Hazards <i>H315 (100%): Causes skin irritation [Warning Skin corrosion/irritation]</i> <i>H317 (96.26%): May cause an allergic skin reaction [Warning Sensitization, Skin]</i></p> <p>Health Hazard SYMPTOMS: Symptoms of exposure to this compound may include irritation and sensitization of the skin. It may also cause eye irritation and damage.</p> <p>The substance <i>is irritating to the skin</i> and is mildly irritating to the eyes. IPCS, CEC; International Chemical Safety Card on d-Limonene. (April 2005). Available from, as of February 3, 2006: http://www.inchem.org/documents/icsc/icsc/eics0918.htm from HSDB</p> <p>https://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+4186</p> <p>HUMAN EXPOSURE AND TOXICITY: Skin irritation or sensitizing potential was reported following widespread use of this agent in various consumer products. <i>In humans, oxidation products or metabolites of d-limonene were shown to act as skin irritants. The potential occurrence of skin irritation necessitates regulation of this chemical as an ingredient in cosmetics.</i></p> <p>http://www.thegoodscentscompany.com/data/rw1013772.html#tosafty European information : Most important hazard(s): <i>R 36/38 - Irritating to skin and eyes.</i> <i>R 43 - May cause sensitization by skin contact.</i></p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i> <i>Skin sensitisation (Category 1), H317</i></p> <p>https://www.ewg.org/guides/substances/151421-dLimonene#.W37iluhKiUk Recognized by the European Union as a skin allergen Allergen list - EU Cosmetics Directive</p> <p>https://cosmeticsinfo.org/ingredient/limonene-0 The safety of Limonene has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established. The IFRA Standard restricts the use of Limonene in fragrances because of potential sensitization.</p> <p>In Europe, Limonene is included on the list of "allergenic" substances. The European Cosmetics Directive requires manufacturers of cosmetics and personal care products to indicate the presence of certain "allergenic" substances in the list of ingredients if they are present above certain levels in the product (see Annex III). The presence of Limonene must be indicated in the list of ingredients when its concentration exceeds: 0.001% in leave-on the skin products 0.01% in products that are rinsed off the skin</p>
1-(2,6,6-Trimethylcyclohex-2-en-1-yl)pent-1-en-3-one	Y		<p>https://pubchem.ncbi.nlm.nih.gov/compound/5375218#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements</p> <p><i>H315 (17.53%): Causes skin irritation [Warning Skin corrosion/irritation]</i> <i>H317 (81.57%): May cause an allergic skin reaction [Warning Sensitization, Skin]</i></p>

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			http://www.thegoodscentscompany.com/data/rw1032741.html#tosaftey European information : Most important hazard(s): <i>R 36/37/38 - Irritating to eyes, respiratory system, and skin.</i>
1,2-Dimethoxy-4-prop-1-en-1-ylbenzene	Y		http://www.thegoodscentscompany.com/data/rw1011132.html#tosaftey European information : Most important hazard(s): <i>S 24/25 - Avoid contact with skin and eyes.</i> https://chem.nlm.nih.gov/chemidplus/rn/93-16-3 <i>Skin/eye irritant</i> https://pubchem.ncbi.nlm.nih.gov/compound/cis-Methylisoeugenol#section=Hazards-Identification Signal: Warning GHS Hazard Statements <i>H317 (86.67%): May cause an allergic skin reaction [Warning Sensitization, Skin]</i>
1, 7, 7-Trimethylbicyclo[2.2.1]heptan-2-ol (Isocamphol, Isobornyl alcohol)	Y		https://chem.nlm.nih.gov/chemidplus/rn/124-76-5 <i>Skin/eye irritant</i> http://www.thegoodscentscompany.com/data/rw1002092.html#tosaftey European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 36/37/38 - Irritating to eyes, respiratory system, and skin.</i> <i>R 42/43 - May cause sensitization by inhalation and skin contact.</i> GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i>
1-Acetonaphthone	Y		https://pubchem.ncbi.nlm.nih.gov/compound/1-Acetonaphthone#section=Safety-and-Hazards GHS Hazard Statements <i>H315 (11.59%): Causes skin irritation [Warning Skin corrosion/irritation]</i> <i>H317 (80.69%): May cause an allergic skin reaction [Warning Sensitization, Skin]</i>
1-Benzazole (Indole)	Y	Y	https://pubchem.ncbi.nlm.nih.gov/compound/798#section=Safety-and-Hazards GHS Hazard Statements <i>H311 (98.88%): Toxic in contact with skin [Danger Acute toxicity, dermal]</i> https://chem.nlm.nih.gov/chemidplus/rn/120-72-9 <i>Skin/eye irritant</i> http://www.thegoodscentscompany.com/data/rw1006511.html#tosaftey European information : Most important hazard(s):

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p><i>R 21/22 - Harmful in contact with skin and if swallowed.</i> <i>R 37/38 - Irritating to respiratory system and skin.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i></p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i></p>
1-Cedr-8-en-9-yl ethenone (Methyl cedryl ketone, vertofix)	Y	Y	<p>https://pubchem.ncbi.nlm.nih.gov/compound/107065#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements</p> <p><i>H317 (94.26%): May cause an allergic skin reaction [Warning Sensitization, Skin]</i> http://www.thegoodscentscompany.com/data/rw1026472.html#tosaftey</p> <p>European information : Most important hazard(s): Xi - Irritant <i>R 36/38 - Irritating to skin and eyes.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i></p>
1-Methoxy-4-methylbenzene (p-methylanisole)		Y	<p>https://pubchem.ncbi.nlm.nih.gov/compound/7731#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements <i>H315 (99.65%): Causes skin irritation [Warning Skin corrosion/irritation]</i></p> <p>https://chem.nlm.nih.gov/chemidplus/rn/104-93-8 <i>Skin/eye irritant</i></p> <p>http://www.thegoodscentscompany.com/data/rw1003932.html#tosaftey European information : Most important hazard(s): <i>R 38 - Irritating to skin.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i></p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i></p>
1-Methyl-1-(4-methylcyclohex-3-en-1-yl)ethyl acetate (alpha-Terpinyl acetate)	Y		<p>http://www.thegoodscentscompany.com/data/rw1011272.html#tosaftey European information : Most important hazard(s): Xi - Irritant <i>R 36/38 - Irritating to skin and eyes.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i></p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i></p> <p>GHS Label elements, including precautionary statements Signal word Warning</p> <p>Hazard statement(s)</p>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<i>H315 - Causes skin irritation</i>
2,6-Dimethylheptan-2-ol (2,6-Dimethyl-2-heptanol Freesia heptanol Dimetol (Givaudan))		Y	https://pubchem.ncbi.nlm.nih.gov/compound/83268#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements <i>H315 (100%): Causes skin irritation [Warning Skin corrosion/irritation]</i> https://chem.nlm.nih.gov/chemidplus/rn/13254-34-7 <i>Skin/eye irritant</i> http://www.thegoodscentscompany.com/data/rw1024471.html#tosaftey European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 36/38 - Irritating to skin and eyes.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i>
2-Isopropenyl-5-methylcyclohexanol (Isopulegol)	Y		https://pubchem.ncbi.nlm.nih.gov/compound/24585#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements <i>H315 (82.31%): Causes skin irritation [Warning Skin corrosion/irritation]</i> http://www.thegoodscentscompany.com/data/rw1449811.html#tosaftey European information : Most important hazard(s): <i>Xn - Harmful.</i> <i>R 36/38 - Irritating to skin and eyes.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i>
2-Isopropyl-5-methylcyclohexanol (Menthol, Menthol, (1 alpha, 2 beta, 5 alpha)-Isomer)	Y		https://pubchem.ncbi.nlm.nih.gov/compound/1254#section=GHS-Classification Signal: Warning GHS Hazard Statements <i>H315 (97.9%): Causes skin irritation [Warning Skin corrosion/irritation]</i> Health Hazard SYMPTOMS: Symptoms of exposure to this compound may include irritation of the skin, eyes, mucous membranes and upper respiratory tract. from CAMEO Chemicals https://chem.nlm.nih.gov/chemidplus/rn/89-78-1 <i>Skin/eye irritant</i> http://www.thegoodscentscompany.com/data/rw1029672.html#tosaftey European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 37/38 - Irritating to respiratory system and skin.</i> <i>R 41 - Risk of serious damage to eyes.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i>
2-Nonanone,3-(hydroxymethyl) (2-Acetyl-1-octanol Herbal ketone Methyl lavender ketone - (IFF))		Y	https://pubchem.ncbi.nlm.nih.gov/compound/106823#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements <i>H315 (100%): Causes skin irritation [Warning Skin corrosion/irritation]</i>
2-Octanol,2,6-dimethyl (2,6-Dimethyloctan-2-ol)		Y	https://pubchem.ncbi.nlm.nih.gov/compound/86751#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements <i>H315 (100%): Causes skin irritation [Warning Skin corrosion/irritation]</i> http://www.thegoodscentscompany.com/data/rw1030292.html#tosaftey European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 36/38 - Irritating to skin and eyes.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i>
2-Phenylethyl 3-methylbutanoate (Phenethyl Isovalerate)	Y		http://www.thegoodscentscompany.com/data/rw1010091.html#tosaftey European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 36/38 - Irritating to skin and eyes.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i>
2-Phenylethyl formate (Phenethyl formate formic acid, 2-phenylethyl ester)	Y		https://pubchem.ncbi.nlm.nih.gov/compound/7711#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements <i>H317 (100%): May cause an allergic skin reaction [Warning Sensitization, Skin]</i> http://www.thegoodscentscompany.com/data/rw1026431.html#tosaftey European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 36/38 - Irritating to skin and eyes.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i>
2-Phenylethyl phenylacetate (Phenethyl phenylacetate)	Y		http://www.thegoodscentscompany.com/data/rw1010111.html#tosaftey European information : Most important hazard(s): <i>Xi N - Irritant, Dangerous for the environment.</i> <i>R 36/38 - Irritating to skin and eyes.</i> GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i>

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p>H315 (95.35%): Causes skin irritation [Warning Skin corrosion/irritation] H317 (99.55%): May cause an allergic skin reaction [Warning Sensitization, Skin]</p> <p>Skin, Eye, and Respiratory Irritations <i>/Skin/ moderately irritating.</i> Opdyke, D.L.J. (ed.). Monographs on Fragrance Raw Materials. New York: Pergamon Press, 1979., p. 235 from HSDB</p> <p>Toxicity Summary HUMAN EXPOSURE AND TOXICITY: Adult male volunteers with no known allergic reactions were patch-tested on their back for 48 hr with 32% citronellol. After 48 hr, patches were removed and the skin was cleaned of any residual test material. Moderate irritation was observed. A patch test using a 1% concentration of citronellol in acetone gave a positive reaction in subjects allergic to citronella oil. ANIMAL STUDIES: Citronellol applied full strength to intact or abraded rabbit skin for 24 hr under occlusion was moderately irritating. Severe irritation was observed in rabbits and guinea pigs exposed to 100% compound (unoccluded) for 24, 48 or 72 hr. from HSDB</p> <p>https://chem.nlm.nih.gov/chemidplus/rn/106-22-9 <i>Skin/eye irritant</i></p> <p>https://www.ewg.org/guides/substances/1285-CITRONELLOL#.W38ssuhKiUk Recognized by the European Union as a skin allergen Allergen list - EU Cosmetics Directive</p> <p>The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p> <p>The European Commission's Scientific Committee on Consumer Safety reports this substance shows some evidence of causing contact allergy in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p> <p>https://cosmeticsinfo.org/ingredient/citronellol-0 The safety of Citronellol has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established. The IFRA Standard restricts the use of Citronellol in fragrances because of potential sensitization.</p> <p>http://www.thegoodscentscompany.com/data/rw1007032.html#tosaftey European information : Most important hazard(s):</p> <p><i>R 36/38 - Irritating to skin and eyes.</i> <i>R 43 - May cause sensitisation by skin contact.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i></p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i> <i>Skin sensitisation (Category 1), H317</i></p>
3, 7-Dimethylocta-2,6-dien-1-yl acetate	Y		Neryl Acetate

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
(Neryl Acetate Nerol Acetate)			https://pubchem.ncbi.nlm.nih.gov/compound/1549025#section=GHS-Classification Signal: Warning GHS Hazard Statements <i>H315 (15.29%): Causes skin irritation [Warning Skin corrosion/irritation]</i> <i>H317 (15.29%): May cause an allergic skin reaction [Warning Sensitization, Skin]</i> Skin, Eye, and Respiratory Irritations In human patch test, geraniol @ 32% concn was severely irritating & geranyl acetate mildly irritating. Motoyoski et al; Cosmet Toiletries 94(8): 41 (1979) from HSDB http://www.thegoodscentscompany.com/data/rw1033552.html#tosaftey European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 36/38 - Irritating to skin and eyes.</i>
3,7-Dimethylocta-2,6-dien-1-yl benzoate (<i>Trans</i> -3,7-Dimethylocta-2,6-dien-1-yl benzoate, Geranyl Benzoate)	Y		Trans-3,7-Dimethylocta-2,6-dien-1-yl benzoate or Geranyl Benzoate ??? https://pubchem.ncbi.nlm.nih.gov/compound/5353011#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements <i>H315 (100%): Causes skin irritation [Warning Skin corrosion/irritation]</i> http://www.thegoodscentscompany.com/data/rw1024871.html#tosaftey European information : Most important hazard(s): S 24/25 - Avoid contact with skin and eyes.
3-Methyl-1H-indole (Skatole)	Y		https://pubchem.ncbi.nlm.nih.gov/compound/6736#section=GHS-Classification Signal: Warning GHS Hazard Statements with hazard statement code(s): <i>H315 (96.3%): Causes skin irritation [Warning Skin corrosion/irritation]</i> http://www.thegoodscentscompany.com/data/rw1006331.html#tosaftey European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 36/37/38 - Irritating to eyes, respiratory system, and skin.</i> S 20/21 - When using do not eat, drink or smoke. S 24/25 - Avoid contact with skin and eyes.
3-Methyl-5-(2,2,3-trimethylcyclopent-3-en-1-yl)pentan-2-ol (Sandal pentanol, Sandalore)	Y		https://pubchem.ncbi.nlm.nih.gov/compound/103212#section=Safety-and-Hazards Signal: Warning http://www.thegoodscentscompany.com/data/rw1026291.html#tosaftey European information : Most important hazard(s):

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p><i>Xi - Irritant</i> <i>R 36/37/38 - Irritating to eyes, respiratory system, and skin.</i></p>
3-Methylbutyl salicylate <i>(Isoamyl Salicylate)</i>		Y	<p>http://www.thegoodscentscompany.com/data/rw1006772.html#tosaftey</p>
3-Phenylpropan-1-ol	Y		<p>https://pubchem.ncbi.nlm.nih.gov/compound/31234#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements</p> <p><i>H315 (98.51%): Causes skin irritation [Warning Skin corrosion/irritation]</i></p> <p>Toxicity Summary HUMAN EXPOSURE AND TOXICITY: In a multicenter study, 218 fragrance sensitive patients with proven contact dermatitis were patch tested. Reactions (0.9%) in fragrance sensitive patients were observed with 3-phenylpropanol at 5% in petrolatum. ANIMAL STUDIES: In an irritation study in rabbits 3-phenylpropanol was applied for 24 hr under occlusion at dose levels of 2.5 and 5 g/kg. At 2.5 g/kg, moderate erythema and slight to moderate edema were observed. At 5 g/kg, moderate to severe erythema and moderate edema were observed. In another study in rabbits, 3-phenyl-1-propanol was applied for 24 hr under occlusion at 5 g/kg. Moderate to severe erythema, severe edema, scaling and necrosis were observed. A 0.5 mL aliquot of 3-phenylpropanol was applied to intact and abraded skin for 24 hr under occlusion. Moderate irritation was observed. Necrosis was also observed. from HSDB</p> <p>https://chem.nlm.nih.gov/chemidplus/rn/122-97-4 <i>Skin/eye irritant</i></p> <p>http://www.thegoodscentscompany.com/data/rw1010172.html#tosaftey European information : Most important hazard(s): Xi - Irritant R 36/38 - Irritating to skin and eyes. S 24/25 - Avoid contact with skin and eyes.</p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i></p>
4-(2,6,6-Trimethylcyclohex-2-en-1-yl)but-3-en-2-one <i>(alpha-ionone)</i>	Y		<p>https://pubchem.ncbi.nlm.nih.gov/compound/5282108#section=Safety-and-Hazards Signal: Danger GHS Hazard Statements</p> <p>Skin, Eye, and Respiratory Irritations <i>alpha-Ionone was found to be a moderate /skin/ irritant.</i> Lalko J et al; Food Chem Toxicol 45 Suppl 1: S235-40 (2007) from HSDB</p> <p>Toxicity Summary HUMAN EXPOSURE AND TOXICITY: AI (32 % in acetone) was found to be a moderate irritant. No reactions were observed with 1% AI; 5% AI produced one irritant/questionable reaction. ANIMAL STUDIES: No skin irritation was observed in miniature swine using neat AI. In guinea pigs AI was reported to be <i>moderately irritating in skin test</i>. AI produced <i>severe skin irritation reaction in rabbits</i>. AI was tested in a 90-days oral toxicity study using male and female rats.</p>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			<p>from HSDB</p> <p>http://www.thegoodscentscompany.com/data/rw1011952.html#tosafy</p> <p>European information :</p> <p>Most important hazard(s):</p> <p><i>Xi - Irritant</i></p> <p><i>R 36/38 - Irritating to skin and eyes.</i></p> <p><i>R 42/43 - May cause sensitization by inhalation and skin contact.</i></p> <p><i>S 24/25 - Avoid contact with skin and eyes.</i></p>
<p>4,7-Methano-1H-indenol, 3a,4,5,6, 7, 7a-hexahydro-, propanoate</p> <p>(Tricyclodeceny Propionate)</p>		Y	<p>https://pubchem.ncbi.nlm.nih.gov/compound/86579#section=Safety-and-Hazards</p> <p>Signal: Warning</p> <p>GHS Hazard Statements</p> <p>https://chem.nlm.nih.gov/chemidplus/rn/17511-60-3</p> <p><i>Skin/eye irritant</i></p> <p>https://www.ewg.org/guides/substances/6105-TRICYCLODECENYLPROPIONATE#.W4QRzuhKiUk</p> <p>The European Commission's Scientific Committee on Consumer Safety reports this substance lacks data on contact allergy in humans. IOpinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p> <p>http://www.thegoodscentscompany.com/data/rw1011151.html#tosafy</p> <p>European information :</p> <p>Most important hazard(s):</p> <p><i>Xi - Irritant</i></p> <p><i>R 36/38 - Irritating to skin and eyes.</i></p> <p><i>S 24/25 - Avoid contact with skin and eyes.</i></p>
<p>4-Methyl phenyl 2-methylpropanoate</p> <p>(p-Tolyl isobutyrate P-Cresyl isobutyrate)</p>	Y		<p>http://www.thegoodscentscompany.com/data/rw1035021.html#tosafy</p> <p>European information :</p> <p>Most important hazard(s):</p> <p><i>Xi - Irritant</i></p> <p><i>R 36/37/38 - Irritating to eyes, respiratory system, and skin.</i></p>
<p>5-Isopropenyl-2-methylcyclohex-2-en-1-one</p> <p>(Carvone)</p>	Y		<p>https://pubchem.ncbi.nlm.nih.gov/compound/7439#section=Hazards-Identification</p> <p>Signal: Danger</p> <p>GHS Hazard Statements</p> <p><i>H315 (99.37%): Causes skin irritation [Warning Skin corrosion/irritation]</i></p> <p><i>H317 (92.11%): May cause an allergic skin reaction [Warning Sensitization, Skin]</i></p> <p>Toxicity Summary</p> <p>HUMAN EXPOSURE AND TOXICITY: The sensitizing potential of l-carvone has been considered low, but it has occasionally caused contact allergy in users of spearmint toothpaste and chewing gum. ANIMAL STUDIES: Clinical signs after acute exposure in mice and rats were different depending on the route of exposure.. After acute dermal exposure no systemic or skin effects were observed</p> <p>from HSDB</p>
<p>8-Cyclohexadecen-1-one</p>	Y		<p>https://pubchem.ncbi.nlm.nih.gov/compound/534634#section=Safety-and-Hazards</p> <p>Signal: Warning</p> <p>GHS Hazard Statements</p> <p><i>H315 (68.75%): Causes skin irritation [Warning Skin corrosion/irritation]</i></p>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower															
Chemical	Baby Powder	Shower-to-Shower													
Acetic acid, p-tert-butylcyclohexyl (4-Tert-butylcyclohexyl acetate)		Y	https://chem.nlm.nih.gov/chemidplus/rn/32210-23-4 <i>Skin/eye irritant</i> http://www.thegoodscentscompany.com/data/rw1001372.html#tosaftey GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i>												
Acetic acid, phenylmethyl ester (Benzyl acetate)	Y		https://pubchem.ncbi.nlm.nih.gov/compound/8785#section=Hazards-Identification Signal: Danger GHS Hazard Statements <i>H315: Causes skin irritation [Warning Skin corrosion/irritation]</i> Health Hazard Harmful if inhaled. May be harmful if swallowed or absorbed through the skin. Vapor or mist is irritating to the eyes, mucous membrane and upper respiratory tract. (USCG, 1999) from CAMEO Chemicals Skin, Eye, and Respiratory Irritations ... Irritating to skin, eyes, respiratory tract. Budavari, S. (ed.). The Merck Index - Encyclopedia of Chemicals, Drugs and Biologicals. Rahway, NJ: Merck and Co., Inc., 1989., p. 176 from HSDB NIOSH Toxicity Data <table><tr><th>Measurement</th><th>System</th><th>Route/Organism</th><th>Dose</th><th>Effect</th><th>Date</th></tr><tr><td>Skin and Eye Irritation</td><td></td><td>skin /rabbit</td><td>100 mg/24H</td><td>moderate</td><td>October 2017</td></tr></table> Skin Symptoms Dry skin. from ILO-ICSC https://chem.nlm.nih.gov/chemidplus/rn/140-11-4 <i>Skin/eye irritant</i> https://www.ewg.org/guides/substances/640-BENZYLACETATE#.W4QdrehKiUk The European Commission's Scientific Committee on Consumer Safety reports this substance shows negative results for causing contact allergy in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive http://www.thegoodscentscompany.com/data/rw1001612.html#tosaftey European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 36/37/38 - Irritating to eyes, respiratory system, and skin.</i>	Measurement	System	Route/Organism	Dose	Effect	Date	Skin and Eye Irritation		skin /rabbit	100 mg/24H	moderate	October 2017
Measurement	System	Route/Organism	Dose	Effect	Date										
Skin and Eye Irritation		skin /rabbit	100 mg/24H	moderate	October 2017										

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i>
Aldehyde C-7 (Heptanal)	Y		https://pubchem.ncbi.nlm.nih.gov/compound/8130#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements H315 (99.71%): Causes skin irritation [Warning Skin corrosion/irritation] https://chem.nlm.nih.gov/chemidplus/rn/111-71-7 Skin/eye irritant http://www.thegoodscentscompany.com/data/rw1014291.html#tosaftey European information : Most important hazard(s): Xi - Irritant R 36/37/38 - Irritating to eyes, respiratory system, and skin. R 50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Alpha-Isomethyl Ionone	Y		https://pubchem.ncbi.nlm.nih.gov/compound/5372174#section=Hazards-Identification Signal: Warning GHS Hazard Statements H315 (80.27%): Causes skin irritation [Warning Skin corrosion/irritation] H317 (90.98%): May cause an allergic skin reaction [Warning Sensitization, Skin] http://www.thegoodscentscompany.com/data/rw1594731.html#tosaftey (50% minimum alpha-isomethyl ionone) European information : Most important hazard(s): Xi N - Irritant, Dangerous for the environment. R 38 - Irritating to skin. R 43 - May cause sensitisation by skin contact. GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) Skin sensitisation (Category 1), H317 (70% minimum alpha-isomethyl ionone) European information : Most important hazard(s): Xi - Irritant R 38 - Irritating to skin. 02 - Keep out of the reach of children. S 24/25 - Avoid contact with skin and eyes. (80% minimum alpha-isomethyl ionone) European information : Most important hazard(s): Xi - Irritant R 38 - Irritating to skin. S 24/25 - Avoid contact with skin and eyes.

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p>(90% minimum alpha-isomethyl ionone) European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 38 - Irritating to skin.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i></p> <p>https://cosmeticsinfo.org/ingredient/alpha-isomethyl-ionone-0 The safety of Alpha-Isomethyl Ionone has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established. The IFRA Standard restricts the use of mixed isomers of methyl ionone (including Alpha-Isomethyl Ionone) in fragrances because of potential sensitization.</p> <p>The Flavor and Extract Manufacturers Association Expert Panel has reviewed the safety of Alpha-Isomethyl Ionone and determined that it was Generally Recognized as Safe (GRAS) for use as a flavoring substance. In Europe, Alpha-Isomethyl Ionone is included on the list of "allergenic" substances.</p> <p>The European Cosmetics Regulation requires manufacturers of cosmetics and personal care products to indicate the presence of certain "allergenic" substances in the list of ingredients if they are present above certain levels in the product (see Annex III). The presence of Alpha-Isomethyl Ionone must be indicated in the list of ingredients when its concentration exceeds: 0.001% in leave-on the skin products 0.01% in products that are rinsed off the skin.</p> <p>Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013</p> <p>https://www.ewg.org/skindeep/ingredient/700295/ALPHA-ISOMETHYL_IONONE/#.W4QmbOhKiUI Allergies/immunotoxicity Possible human immune system toxicant or allergen SCCPNFP (Scientific Committee On Cosmetic Products And Non-Food Products). 1999. Opinion Concerning Fragrance Allergy In Consumers. . SCCNFP/0017/98 Final, December 1999; and SCCPNFP (Scientific Committee On Cosmetic Products And Non-Food Products). 2000. An Initial List Of Perfumery Materials Which Must Not Form Part Of Fragrances Compounds Used In Cosmetic Products. SCCNFP/0320/00, final May 2000.</p>
<p>Amyl Cinnamal</p> <p>(<i>alpha-Amyl cinnamaldehyde</i></p> <p><i>alpha-pentylcinnamaldehyde</i>)</p>	Y	Y	<p>https://chem.nlm.nih.gov/chemidplus/rn/122-40-7 <i>Skin/eye irritant</i></p> <p>https://pubchem.ncbi.nlm.nih.gov/compound/1623625#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements</p> <p>H317 (98.8%): May cause an allergic skin reaction [Warning Sensitization, Skin]</p> <p>Skin, Eye, and Respiratory Irritations <i>A severe skin irritant.</i> Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 251 from HSDB</p>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p>https://www.ewg.org/guides/substances/368-AMYL CINNAMALDEHYDE#.W4QozuhKiUk Recognized by the European Union as a skin allergen Allergen list - EU Cosmetics Directive</p> <p>The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p> <p>EPA's review of industry submitted toxicity data and the potential for human exposure concludes that this substance poses a moderate risk for human health. EPA Hazard-Based Prioritizations - Risks - Environmental Protection Agency (EPA)</p> <p>https://cosmeticsinfo.org/ingredient/amyl-cinnamal-0 The safety of Amyl Cinnamal has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established.</p> <p>The IFRA Standard restricts the use of Amyl Cinnamal in fragrances because of potential sensitization.</p> <p>More safety Information: Link to FDA Code of Federal Regulations for alpha-amyl cinnamic aldehyde (Amyl Cinnamal): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.515&SearchTerm=cinnamaldehyde</p> <p>The Joint FAO/WHO Expert Committee on Food Additives (JECFA) concluded that Amyl Cinnamal does not present a safety concern at current levels of intake when used as a flavoring agent.</p> <p>Link to the JECFA safety evaluation of Amyl Cinnamal: http://www.inchem.org/documents/jecfa/jecval/jec_123.htm</p> <p>The Flavor and Extract Manufacturers Association Expert Panel has reviewed the safety of Amyl Cinnamal and determined that it was Generally Recognized as Safe for use as a flavoring substance. In Europe, Amyl Cinnamal is included on the list of "allergenic" substances.</p> <p>The European Cosmetics Directive requires manufacturers of cosmetics and personal care products to indicate the presence of certain "allergenic" substances in the list of ingredients if they are present above certain levels in the product (see Annex III). The presence of Amyl Cinnamal must be indicated in the list of ingredients when its concentration exceeds: 0.001% in leave-on the skin products 0.01% in products that are rinsed off the skin</p> <p>Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013</p> <p>http://www.thegoodscentscompany.com/data/rw1001011.html#tosaftey European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 36/37/38 - Irritating to eyes, respiratory system, and skin.</i> <i>R 43 - May cause sensitisation by skin contact.</i></p> <p>Hazards identification</p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) Skin sensitisation (Category 1), H317</p>
Anisaldehyde	Y		<p>https://chem.nlm.nih.gov/chemidplus/rn/123-11-5</p>

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower															
Chemical	Baby Powder	Shower-to-Shower													
(P-Anisaldehyde)			<p><i>Skin/eye irritant</i></p> <p>http://www.thegoodscentscompany.com/data/rw1001272.html#tosafy</p> <p>European information : Most important hazard(s): Xi - Irritant R 36/38 - Irritating to skin and eyes.</p> <p>Hazards identification</p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Acute toxicity, dermal (Category 5), H313</i> <i>Skin corrosion/irritation (Category 3), H316</i></p>												
Benzaldehyde	Y		<p>https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr348.pdf</p> <p>https://chem.nlm.nih.gov/chemidplus/rn/100-52-7 <i>Skin/eye irritant</i></p> <p>https://pubchem.ncbi.nlm.nih.gov/compound/240#section=GHS-Classification</p> <p>Signal: Warning GHS Hazard Statements <i>H312 (52%): Harmful in contact with skin [Warning Acute toxicity, dermal]</i> <i>H315 (48%): Causes skin irritation [Warning Skin corrosion/irritation]</i></p> <p>Health Hazard Inhalation of concentrated vapor may irritate eyes, nose and throat. Liquid is irritating to the eyes. <i>Prolonged contact with the skin may cause irritation. (USCG, 1999)</i> from CAMEO Chemicals</p> <p>Skin, Eye, and Respiratory Irritations <i>A skin irritant.</i> Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 353 from HSDB</p> <p>NIOSH Toxicity Data</p> <table><tr><th>Measurement</th><th>System</th><th>Route/Organism</th><th>Dose</th><th>Effect</th><th>Date</th></tr><tr><td>Skin and Eye Irritation</td><td></td><td>skin /rabbit</td><td>500 mg/24H</td><td>moderate</td><td>April 2017</td></tr></table> <p>Health Effects <i>Irritation-Eyes, Nose, Throat, Skin---Moderate (HE15)</i> from OSHA Chemical Sampling Information</p> <p>Symptoms Irritation of eyes, skin, nose, throat; contact dermatitis; INGES. ACUTE: sore throat</p>	Measurement	System	Route/Organism	Dose	Effect	Date	Skin and Eye Irritation		skin /rabbit	500 mg/24H	moderate	April 2017
Measurement	System	Route/Organism	Dose	Effect	Date										
Skin and Eye Irritation		skin /rabbit	500 mg/24H	moderate	April 2017										

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p>from OSHA Chemical Sampling Information</p> <p>Skin Symptoms Redness. from ILO-ICSC</p> <p>Toxicity Summary HUMAN EXPOSURE AND TOXICITY: It may cause contact dermatitis.. ANIMAL STUDIES: from HSDB</p> <p>https://www.ewg.org/guides/substances/7337-BENZALDEHYDE#.W4QxU-hKiUk The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p> <p>https://cosmeticsinfo.org/ingredient/benzaldehyde-0</p> <p>FDA: Link to the Code of Federal Regulations for Benzaldehyde https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=182.60&SearchTerm=benzaldehyde</p> <p>Benzaldehyde may be used in cosmetics and personal care products marketed in Europe according to the general provisions of the Cosmetics Regulation of the European Union.</p> <p>Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013</p> <p>The Joint FAO/WHO Expert Committee on Food Additives has established an Acceptable Daily Intake of 0-5 mg Benzaldehyde/kg body weight. No safety concern was indicated at current levels of intake when used as a flavoring agent. http://www.inchem.org/documents/jecfa/jecval/jec_176.htm</p> <p>http://www.thegoodscentscompany.com/data/rw1001491.html#tosaftey European information : Most important hazard(s): Xn - Harmful. S 24 - Avoid contact with skin.</p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i> <i>Skin sensitisation (Category 1), H317</i></p>
Benzaldehyde, 2-hydroxy- (Salicylaldehyde)	Y		<p>https://pubchem.ncbi.nlm.nih.gov/compound/6998#section=Safety-and-Hazards</p> <p>Signal: Warning GHS Hazard Statements <i>H312 (49.04%): Harmful in contact with skin [Warning Acute toxicity, dermal]</i> <i>H315 (53.07%): Causes skin irritation [Warning Skin corrosion/irritation]</i></p> <p>Health Hazard LIQUID: Irritating to skin and eyes. Harmful if swallowed. (USCG, 1999) from CAMEO Chemicals</p>

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			https://chem.nlm.nih.gov/chemidplus/rn/90-02-8 <i>Skin/eye irritant</i> http://www.thegoodscentscompany.com/data/rw1028641.html#tosaftey European information : Most important hazard(s): Xn - Harmful. R 21/22 - Harmful in contact with skin and if swallowed. R 36/38 - Irritating to skin and eyes. S 24/25 - Avoid contact with skin and eyes.
Benzene, 1,3-dimethoxy- <i>(meta-dimethyl hydroquinone</i> <i>m-dimethoxybenzene)</i>	Y		https://pubchem.ncbi.nlm.nih.gov/compound/9025#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements H312 (50%): Harmful in contact with skin [Warning Acute toxicity, dermal] H315 (50%): Causes skin irritation [Warning Skin corrosion/irritation] http://www.thegoodscentscompany.com/data/rw1027111.html#tosaftey European information : Most important hazard(s): Xi - Irritant R 36/38 - Irritating to skin and eyes. S 24/25 - Avoid contact with skin and eyes.
Benzene, ethenyl- <i>(Styrene, vinylbenzene)</i>	Y		https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/FR673.pdf https://chem.nlm.nih.gov/chemidplus/rn/100-42-5 <i>Skin/eye irritant</i> https://pubchem.ncbi.nlm.nih.gov/compound/styrene#section=Safety-and-Hazards Signal: Danger GHS Hazard Statements H315 (100%): Causes skin irritation [Warning Skin corrosion/irritation] Health Hazard Moderate irritation of eyes and skin. High vapor concentrations cause dizziness, drunkenness, and anesthesia. (USCG, 1999) from CAMEO Chemicals Skin, Eye, and Respiratory Irritations Irritating to skin ... Commission of the European Communities. Legislation on Dangerous Substances - Classification and Labelling in the European Communities. Vol. II. London and Trotman Ltd., 1989., p. 224 from HSDB NIOSH Toxicity Data

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower									
Chemical	Baby Powder	Shower-to-Shower							
			Measurement	Date	System	Route/Organism	Dose	Effect	
			Skin and Eye Irritation	October 2017		eye /human	50 ppm	mild	
			Skin and Eye Irritation	October 2017		eye /rabbit	100 mg	severe	
			Skin and Eye Irritation	October 2017		eye /rabbit	100 mg/24H	moderate	
			Skin and Eye Irritation	October 2017		skin /human	500 mg rinse		
			Skin and Eye Irritation	October 2017		skin /rabbit	500 mg open irritation test	mild	
			Skin and Eye Irritation	October 2017		skin /rabbit	100%	moderate	
			Skin Symptoms Redness. Pain. from ILO-ICSC						
Benzeneacetic acid <i>(Phenylacetic Acid)</i>	Y		https://pubchem.ncbi.nlm.nih.gov/compound/999#section=Toxicity NIOSH Toxicity Data Skin and Eye Irritation November 2009 eye /rabbit 100 mg/24H moderate Skin Symptoms Redness. from ILO-ICSC Toxicity Summary HUMAN STUDIES: Inhalation exposure leads to cough, sore throat.Skin exposure leads to redness. from HSDB http://www.thegoodscentscompany.com/data/rw1009911.html#tosaftey European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 36/37/38 - Irritating to eyes, respiratory system, and skin.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i> GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i>						
Benzeneacetic acid, methyl ester	Y		https://chem.nlm.nih.gov/chemidplus/rn/101-41-7 <i>Skin/eye irritant</i>						

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
(Methyl 2-Phenylacetate) Methyl phenylacetate)			<p>https://pubchem.ncbi.nlm.nih.gov/compound/7559#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements</p> <p><i>H315 (66.67%): Causes skin irritation [Warning Skin corrosion/irritation]</i></p> <p>Skin, Eye, and Respiratory Irritations <i>A skin irritant.</i> Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 2388 from HSDB</p> <p>http://www.thegoodscentscompany.com/data/rw1008431.html#tosaftey European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 36/38 - Irritating to skin and eyes.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i></p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Acute toxicity, dermal (Category 5), H313</i> <i>Skin corrosion/irritation (Category 3), H316</i></p>
Benzoic acid, 2,4-dihydroxy-3,6-dimethyl-, methyl ester (Methyl 3-methylorsellinate)	Y		<p>http://www.thegoodscentscompany.com/data/rw1023372.html#tosaftey European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 36/37/38 - Irritating to eyes, respiratory system, and skin.</i></p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i> <i>H335</i></p>
Benzoic acid, 2-hydroxy-, 2-methylpropyl ester (Isobutyl Salicylate)	Y		<p>http://www.thegoodscentscompany.com/data/rw1006892.html#tosaftey European information : Most important hazard(s): <i>Xn - Harmful.</i> <i>R 36/37/38 - Irritating to eyes, respiratory system, and skin.</i></p>
Benzoic acid, 2-hydroxy-, ethyl ester (Ethyl salicylate)	Y		<p>https://chem.nlm.nih.gov/chemidplus/rn/118-61-6 <i>Skin/eye irritant</i></p> <p>http://www.thegoodscentscompany.com/data/rw1001561.html#tosaftey European information : Most important hazard(s): <i>Xn - Harmful.</i> <i>R 36/37/38 - Irritating to eyes, respiratory system, and skin.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i></p>
Benzophenone		Y	Benzophenones-1, -3, -4, -5, -9, and -11

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			<p>https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PRN475.pdf https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr219.pdf https://cosmeticsinfo.org/ingredient/benzophenone-1</p> <p>The Food and Drug Administration (FDA) has approved the use of Benzophenone-3 and Benzophenone-4 as safe and effective, over-the-counter (OTC) sunscreen ingredients. When used as a sunscreen ingredient in the United States, Benzophenone-3 is called Oxybenzone, and may be used at concentrations up to 6%, and Benzophenone-4 is called Sulisobenzene, and may be used at concentrations up to 10%.</p> <p>FDA: Link to Code of Federal Regulations for Benzophenone-3 (Oxybenzone) and Benzophenone-4 (Sulisobenzene)</p> <p>https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=352&showFR=1</p> <p>Benzophenone-3, listed as Oxybenzone, and Benzophenone-4 and -5, listed as Sulisobenzene and Sulisobenzene Sodium, respectively, are included in Annex VII, Part 1 (UV filter which cosmetic products may contain) of the Cosmetics Directive of the European Union. Oxybenzone may be used at concentrations up to 10%, and products containing 0.5% Oxybenzone when used in sunscreen products must be labeled "contains Oxybenzone." Sulisobenzene and Sulisobenzene Sodium may be used at concentrations up to 5% as Sulisobenzene.</p> <p>There are studies that suggest that some sunscreen ingredients, including Oxybenzone may have activity like the hormone, estrogen. Therefore, the European Commission's Scientific Committee for Cosmetic Products and Non-Food Products Intended for Consumers (SCCNFP) was asked to consider if UV filters as used in sunscreen products have estrogenic effects which have the potential to affect human health. The SCCNFP concluded that UV filters used in sunscreen products allowed in the European market have no estrogenic effects that could potentially affect human health.</p> <p>https://pubchem.ncbi.nlm.nih.gov/compound/3102#section=Exposure-Routes Skin Symptoms Redness. from ILO-ICSC</p> <p>http://www.thegoodscentscompany.com/data/rw1016332.html#tosafty European information : Most important hazard(s): <i>Xi N - Irritant, Dangerous for the environment.</i> <i>R 36/37/38 - Irritating to eyes, respiratory system, and skin.</i></p>
Benzyl Alcohol	Y		<p>https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr323.pdf https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr323.pdf</p> <p>https://chem.nlm.nih.gov/chemidplus/rn/100-51-6 Skin/eye irritant</p> <p>https://pubchem.ncbi.nlm.nih.gov/compound/244#section=Hazards-Identification Signal: Warning GHS Hazard Statements H312 (17.85%): Harmful in contact with skin [Warning Acute toxicity, dermal]</p> <p>Skin, Eye, and Respiratory Irritations A moderate skin and severe eye irritant.</p>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower																																			
Chemical	Baby Powder	Shower-to-Shower																																	
			<p>Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 399 from HSDB</p> <p><i>It is slightly irritating to the skin</i> International Labour Office. Encyclopedia of Occupational Health and Safety. Vols. I&II. Geneva, Switzerland: International Labour Office, 1983., p. 111 from HSDB</p> <p>Vapor: Irritating to eyes, nose and throat. Liquid: Irritating to skin & eyes. U.S. Coast Guard, Department of Transportation. CHRIS - Hazardous Chemical Data. Volume II. Washington, D.C.: U.S. Government Printing Office, 1984-5. from HSDB</p> <p>NIOSH Toxicity Data</p> <table> <tr> <th>Measurement</th><th>System</th><th>Route/Organism</th><th>Dose</th><th>Effect</th><th>Date</th></tr> <tr> <td>Skin and Eye Irritation</td><td></td><td>skin /human</td><td>1%/2D</td><td></td><td>April 2017</td></tr> <tr> <td>Skin and Eye Irritation</td><td></td><td>skin /man</td><td>16 mg/48H</td><td>mild</td><td>April 2017</td></tr> <tr> <td>Skin and Eye Irritation</td><td></td><td>skin /pig</td><td>100%</td><td>moderate</td><td>April 2017</td></tr> <tr> <td>Skin and Eye Irritation</td><td></td><td>skin /rabbit</td><td>100 mg/24H</td><td>moderate</td><td>April 2017</td></tr> </table> <p>Skin Symptoms Redness. from ILO-ICSC</p> <p>Toxicity Summary Toxicity 1250 mg/kg (rat, oral) LD50 400 mg/kg IPR-RAT LD50 2000 mg/kg SKN-RBT LD50 53 mg/kg IVN-RAT LD50 2500 mg/kg ORL-GPG LD50 from DrugBank</p> <p>HUMAN EXPOSURE AND TOXICITY: Benzyl alcohol has been found to be irritating to the skin at levels 3% or greater. Patch test with 0.65% benzyl alcohol did not produce irritation of the skin. ANIMAL STUDIES: In a primary irritation study 10% benzyl alcohol applied in a 24-hour occlusive patch to the back of eight male albino rabbits did not cause irritation. Undiluted benzyl alcohol was moderately irritating when applied to the depilated skin of guinea pigs for 24 hr. from HSDB</p> <p>https://www.ewg.org/guides/substances/641-BENZYLALCOHOL#.W4RkHehKiUk Recognized by the European Union as a skin allergen Allergen list - EU Cosmetics Directive</p>			Measurement	System	Route/Organism	Dose	Effect	Date	Skin and Eye Irritation		skin /human	1%/2D		April 2017	Skin and Eye Irritation		skin /man	16 mg/48H	mild	April 2017	Skin and Eye Irritation		skin /pig	100%	moderate	April 2017	Skin and Eye Irritation		skin /rabbit	100 mg/24H	moderate	April 2017
Measurement	System	Route/Organism	Dose	Effect	Date																														
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Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			<p>The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p> <p>https://cosmeticsinfo.org/ingredient/benzyl-alcohol</p> <p>The Food and Drug Administration (FDA) includes Benzoic Acid and Sodium Benzoate on its list of direct food substances affirmed as Generally Recognized As Safe (GRAS).</p> <p>The safety of Benzyl Alcohol and Benzyl Benzoate has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN).</p> <p>Based on these evaluations, International Fragrance Association (IFRA) Standards have been established. The IFRA standards restrict the use of Benzyl Alcohol and Benzyl Benzoate in fragrances because of potential sensitization.</p> <p>More safety Information:</p> <p>Clinical data indicated that in a few individuals these ingredients produced non-immunologic contact urticaria and non-immunologic immediate contact reactions, characterized by the appearance of wheals, erythema, and pruritis. In one study, 5% Benzyl Alcohol elicited a reaction, and in another study, 2% Benzoic Acid did likewise. Benzyl Alcohol, however, was not a sensitizer at 10%, nor was Benzoic Acid a sensitizer at 2%.</p> <p>Recognizing that the non-immunologic reactions were strictly cutaneous, likely involve a cholinergic mechanism, it was concluded that these ingredients could be used safely at concentrations up to 5%. Additionally, Benzyl Alcohol was considered safe at up to 10% for use in hair dyes.</p> <p>The limited body exposure, the duration of use, and the frequency of use were considered in concluding that the non-immunologic reactions would not be a concern.</p> <p>Link to FDA Code of Federal Regulations and the Federal Register for Benzyl Alcohol</p> <p>https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.515&SearchTerm=benzyl%20alcohol</p> <p>Benzyl Alcohol may be used as a preservative in cosmetics and personal care products marketed in the European Union at a maximum concentration of 1%. Benzoic Acid and its salts and esters are also permitted for use as preservatives in cosmetics and personal care products at a maximum concentration (expressed as the acid) of 2.5% in rinse-off products (except oral care products), 1.7% in oral care products and 0.5% in leave on products (see Annex VI). Benzyl Alcohol and Benzyl Benzoate are also listed in in Annex III of the European Union Cosmetics Directive. When Benzyl Alcohol or Benzyl Benzoate are used as fragrance ingredients, Annex III requires that the presence of these fragrance ingredients be indicated on the label of the product when used at greater than 0.001% in leave-on products, and greater than 0.01% in rinse-off products.</p> <p>The Joint FAO/WHO Expert Committee on Food Additives has established an Acceptable Daily Intake of 0-5 mg/kg for the sum of Benzoic Acid, Potassium and Sodium Benzoate: http://www.inchem.org/documents/jecfa/jecmono/40abcj02.htm</p>
Benzyl Benzoate	Y	Y	<p>https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PR574.pdf</p> <p>https://pubchem.ncbi.nlm.nih.gov/compound/2345#section=Fire-Hazard</p> <p>Skin, Eye, and Respiratory Irritations</p> <p>Benzyl benzoate is relatively nontoxic but may irritate the skin and eyes.</p>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

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Chemical	Baby Powder	Shower-to-Shower													
			<p>American Medical Association, Council on Drugs. AMA Drug Evaluations Annual 1994. Chicago, IL: American Medical Association, 1994., p. 1615 from HSDB</p> <p>Skin Symptoms MAY BE ABSORBED! Dry skin. Redness. from ILO-ICSC</p> <p>https://www.ewg.org/guides/substances/642-BENZYL BENZOATE#.W4RnX-hKiUk Recognized by the European Union as a skin allergen Allergen list - EU Cosmetics Directive</p> <p>The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p> <p>https://cosmeticsinfo.org/ingredient/benzyl-benzoate SEE BENZYL ALCOHOL</p>												
Benzyl Salicylate	Y	Y	<p>https://pubchem.ncbi.nlm.nih.gov/compound/8363#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements</p> <p>H317 (95.53%): May cause an allergic skin reaction [Warning Sensitization, Skin] H319 (72.34%): Causes serious eye irritation [Warning Serious eye damage/eye irritation]</p> <p>NIOSH Toxicity Data</p> <table><tr><th>Measurement</th><th>Date</th><th>System</th><th>Route/Organism</th><th>Dose</th><th>Effect</th></tr><tr><td>Skin and Eye Irritation</td><td>April 2015</td><td></td><td>skin /human</td><td>2%/2D</td><td></td></tr></table> <p>https://www.ewg.org/guides/substances/645-BENZYL SALICYLATE#.W4RwP-hKiUk Recognized by the European Union as a skin allergen Allergen list - EU Cosmetics Directive</p> <p>The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p> <p>https://cosmeticsinfo.org/ingredient/benzyl-salicylate-0 The Food and Drug Administration (FDA) has approved the use of Benzyl Salicylate as a flavoring agent for direct addition to food. The safety of Benzyl Salicylate has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established. The IFRA Standard restricts the use of Benzyl Salicylate in fragrances because of potential sensitization.</p> <p>More safety Information: See the FDA Code of Federal Regulations for Benzyl Salicylate: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=172.515</p>	Measurement	Date	System	Route/Organism	Dose	Effect	Skin and Eye Irritation	April 2015		skin /human	2%/2D	
Measurement	Date	System	Route/Organism	Dose	Effect										
Skin and Eye Irritation	April 2015		skin /human	2%/2D											

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p>The Joint FAO/WHO Expert Committee on Food Additives (JECFA) concluded that Benzyl Salicylate does not present a safety concern at current levels of intake when used as a flavoring agent. http://www.inchem.org/documents/jecfa/jecval/jec_215.htm</p> <p>The Flavor and Extract Manufacturers Association Expert Panel has reviewed the safety of Benzyl Salicylate and determined that it is Generally Recognized as Safe (GRAS) for use as a flavoring substance. In Europe, Benzyl Salicylate is included on the list of "allergenic" substances. The European Cosmetics Directive requires manufacturers of cosmetics and personal care products to indicate the presence of certain "allergenic" substances in the list of ingredients if they are present above certain levels in the product (see Annex III). The presence of Benzyl Salicylate must be indicated in the list of ingredients when its concentration exceeds: 0.001% in leave-on the skin products 0.01% in products that are rinsed off the skin.</p> <p>Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0012</p> <p>http://www.thegoodscentscompany.com/data/rw1001792.html#tosafy</p> <p>European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 36/37/38 - Irritating to eyes, respiratory system, and skin.</i> <i>R 43 - May cause sensitisation by skin contact.</i> <i>S 24 - Avoid contact with skin.</i></p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) Skin sensitisation (Category 1), H317</p>
Boswellia Carterii Oil (Oils, olibanum Frankincense oil)	Y		<p>No Data</p> <p>http://www.thegoodscentscompany.com/data/es1004051.html#tosafy</p> <p>European information : Most important hazard(s): <i>Xn - Harmful.</i> <i>R 10 - Flammable.</i> <i>R 20/21/22 - Harmful by inhalation, in contact with skin and if swallowed.</i> <i>R 36/37/38 - Irritating to eyes, respiratory system, and skin.</i> <i>R 42/43 - May cause sensitization by inhalation and skin contact.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i></p>
Butanoic acid, ethyl ester (Ethyl n-butyrate Ethyl butanoate)	Y		<p>https://chem.nlm.nih.gov/chemidplus/rn/105-54-4 <i>Skin/eye irritant</i></p> <p>http://www.thegoodscentscompany.com/data/rw1004792.html#tosafy</p> <p>European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 10 - Flammable.</i> <i>R 36/37/38 - Irritating to eyes, respiratory system, and skin.</i></p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i></p>
Butanoic acid, pentyl ester (Amyl Butyrate)	Y		<p>https://pubchem.ncbi.nlm.nih.gov/compound/10890#section=Health-Hazard</p>

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p>Excerpt from ERG Guide 130 [Flammable Liquids (Water-Immiscible / Noxious)]: May cause toxic effects if inhaled or absorbed through skin. Inhalation or contact with material may irritate or burn skin and eyes. Fire will produce irritating, corrosive and/or toxic gases. Vapors may cause dizziness or suffocation. Runoff from fire control or dilution water may cause pollution. (ERG, 2016) from CAMEO Chemicals</p> <p>http://www.thegoodscentscompany.com/data/rw1004151.html#tosaftey</p> <p>European information : Most important hazard(s): Xi - Irritant R 36/37/38 - Irritating to eyes, respiratory system, and skin.</p>
Camphor	Y		<p>https://pubchem.ncbi.nlm.nih.gov/compound/2537#section=Hazards-Identification</p> <p>Signal: Danger GHS Hazard Statements H312 (10.82%): Harmful in contact with skin [Warning Acute toxicity, dermal] H315 (16.04%): Causes skin irritation [Warning Skin corrosion/irritation]</p> <p>Health Hazard Excerpt from ERG Guide 133 [Flammable Solids]: Fire may produce irritating and/or toxic gases. Contact may cause burns to skin and eyes. Contact with molten substance may cause severe burns to skin and eyes. Runoff from fire control may cause pollution. (ERG, 2016) from CAMEO Chemicals</p> <p>Skin, Eye, and Respiratory Irritations The substance is irritating to the eyes, the skin, and the respiratory tract. International Program on Chemical Safety/ Commission of the European Union; International Chemical Safety Card on Camphor. (May 2003). Available from, as of June 30, 2014: http://www.inchem.org/documents/icsc/icsc/eics1021.htm from HSDB</p> <p>Health Effects Irritation-Eye, Nose, Throat, Skin---Moderate (HE15) Acute Toxicity---short-term high hazard effects (HE4) CNS Effects (HE7) from OSHA Chemical Sampling Information</p> <p>Symptoms Irritation of eyes, skin, mucous membrane; nausea, vomiting, diarrhea; headache, dizziness, excitement, epileptiform convulsions; cough, sore throat; Ingestion Acute: Burning sensation in throat and chest; GI symptoms; confusion, seizures, unconsciousness; Skin Absorption; Hepatotoxicity without GI symptoms. from OSHA Chemical Sampling Information</p> <p>irritation eyes, skin, mucous membrane; nausea, vomiting, diarrhea; headache, dizziness, excitement, epileptiform convulsions from The National Institute for Occupational Safety and Health (NIOSH)</p> <p>Skin Symptoms Redness. from ILO-ICSC</p> <p>https://cosmeticsinfo.org/ingredient/camphor-0</p>

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p>The Food and Drug Administration (FDA) includes Camphor in its list of flavoring agents and related substances that are permitted for direct addition to food. Camphor is also approved for use as an active ingredient in Over-The-Counter (OTC) external analgesics, topical antitussive drug products and in anorectal products at concentrations of 0.1 to 3%.</p> <p>More safety Information: The International Programme on Chemical Safety has developed a monograph on the uses and potential effects of Camphor. Fairly large oral doses of Camphor are needed before adverse effects are observed. Carcinogenicity tests have been negative and Camphor is not mutagenic in bacteria. http://www.inchem.org/documents/pims/pharm/camphor.htm</p> <p>Natural Flavoring Substances: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.510&SearchTerm=camphor</p> <p>Antitussive Active Ingredients https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=341.14&SearchTerm=camphor</p> <p>Analgesic, Anesthetic, and Antipruritic Active Ingredients https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=346.16&SearchTerm=camphor</p> <p>Camphor may be used in cosmetics and personal care products marketed in Europe according to the general provisions of the Cosmetics Regulation of the European Union. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013</p> <p>Health Canada permits the use of Camphor in cosmetics and personal care products at concentrations less than or equal to 3%. https://www.canada.ca/en/health-canada/services/cosmetics.html</p> <p>http://www.thegoodscentscompany.com/data/rw1056901.html#tosaftey European information : Most important hazard(s): Xn - Harmful. R 20/21/22 - Harmful by inhalation, in contact with skin and if swallowed. R 36/37/38 - Irritating to eyes, respiratory system, and skin. R 40 - Limited evidence of a carcinogenic effect.</p>
Caproic Acid	Y		<p>https://chem.nlm.nih.gov/chemidplus/rn/142-62-1 <i>Skin/eye irritant</i></p> <p>https://pubchem.ncbi.nlm.nih.gov/compound/8892#section=Hazards-Identification Signal: Danger GHS Hazard Statements</p> <p><i>H311 (23.6%): Toxic in contact with skin [Danger Acute toxicity, dermal]</i> <i>H314 (100%): Causes severe skin burns and eye damage [Danger Skin corrosion/irritation]</i></p> <p>Health Hazard Harmful if swallowed, inhaled, or absorbed through skin. Material is extremely destructive to tissue of mucous membranes and upper respiratory tract, eyes and skin. Inhalation may be fatal as a result of spasm, inflammation and edema of the larynx and bronchia, chemical pneumonitis and pulmonary edema. Symptoms of exposure may include burning sensation, coughing, wheezing, laryngitis, shortness of breath, headache, nausea and vomiting. (USCG, 1999)</p>

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower																													
Chemical	Baby Powder	Shower-to-Shower																											
			<div>from CAMEO Chemicals</div> <div>NIOSH Toxicity Data</div> <table><tr><th>Measurement</th><th>System</th><th>Route/Organism</th><th>Dose</th><th>Effect</th><th>Date</th></tr><tr><td>Skin and Eye Irritation</td><td></td><td>eye /rabbit</td><td>750 µg</td><td>severe</td><td>October 2015</td></tr><tr><td>Skin and Eye Irritation</td><td></td><td>skin /rabbit</td><td>10 mg/24H open irritation test</td><td>mild</td><td>October 2015</td></tr><tr><td>Skin and Eye Irritation</td><td></td><td>skin /rabbit</td><td>465 mg open irritation test</td><td>mild</td><td>October 2015</td></tr></table> <div>Skin Symptoms Redness. Pain. from ILO-ICSC</div> <div>http://www.thegoodscentscompany.com/data/rw1008541.html#tosafy European information : Most important hazard(s): C - Corrosive. R 20/21/22 - Harmful by inhalation, in contact with skin and if swallowed. R 34 - Causes burns. S 24/25 - Avoid contact with skin and eyes. S 28 - After contact with skin, wash immediately with plenty of water.</div>			Measurement	System	Route/Organism	Dose	Effect	Date	Skin and Eye Irritation		eye /rabbit	750 µg	severe	October 2015	Skin and Eye Irritation		skin /rabbit	10 mg/24H open irritation test	mild	October 2015	Skin and Eye Irritation		skin /rabbit	465 mg open irritation test	mild	October 2015
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Carum Carvi (Caraway) Fruit Oil	Y		<div>https://chem.nlm.nih.gov/chemidplus/rn/8000-42-8 <i>Skin/eye irritant</i></div> <div>http://www.thegoodscentscompany.com/data/es1028851.html#tosafy European information : Most important hazard(s): Xi N - Irritant, Dangerous for the environment. R 36/37/38 - Irritating to eyes, respiratory system, and skin. R 43 - May cause sensitisation by skin contact.</div>																										
Cedrol	Y		<div>https://pubchem.ncbi.nlm.nih.gov/compound/65575#section=GHS-Classification Skin, Eye, and Respiratory Irritations ...produced slight /skin/ irritation. Opdyke, D.L.J. (ed.). Monographs on Fragrance Raw Materials. New York: Pergamon Press, 1979., p. 205 from HSDB</div> <div>http://www.thegoodscentscompany.com/data/rw1003031.html#tosafy European information : Most important hazard(s): Xi - Irritant R 36/37/38 - Irritating to eyes, respiratory system, and skin. S 24/25 - Avoid contact with skin and eyes.</div>																										

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
Cedrus Atlantica (Cedarwood) Bark Oil	Y		<p>https://chem.nlm.nih.gov/chemidplus/rn/8023-85-6 <i>Skin/eye irritant</i></p> <p>https://www.ewg.org/guides/substances/1083-CEDRUSATLANTICAATLASCEDARBARKOIL#.W4SHeOhKiUk The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p>
Cinnamal (Cinnamaldehyde)	Y		<p>https://chem.nlm.nih.gov/chemidplus/rn/104-55-2 <i>Skin/eye irritant</i></p> <p>https://pubchem.ncbi.nlm.nih.gov/compound/637511#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements</p> <p><i>H315 (100%): Causes skin irritation [Warning Skin corrosion/irritation]</i> <i>H317 (100%): May cause an allergic skin reaction [Warning Sensitization, Skin]</i></p> <p>Health Hazard ACUTE/CHRONIC HAZARDS: Exposure to this chemical may cause irritation of the skin, eyes, upper respiratory tract and mucous membranes. (NTP, 1992) from CAMEO Chemicals</p> <p>SYMPTOMS: ACUTE/CHRONIC HAZARDS: This chemical may be harmful by inhalation, ingestion or skin absorption. It may cause irritation of the skin, eyes, upper respiratory tract, and mucous membranes. When heated to decomposition it may emit toxic fumes of carbon monoxide and carbon dioxide. (NTP, 1992) from CAMEO Chemicals</p> <p>Skin, Eye, and Respiratory Irritations No primary dermal irritation was observed in human subjects exposed for 48 hours to a solution of a 3% active ingredient, while severe primary dermal irritation was observed in human subjects after exposure to 8% active ingredient. USEPA, Office of Pesticide Programs/ Ombudsman, Biopesticides and Pollution Prevention Division: Active Ingredient Fact Sheet for Cinnamaldehyde (040506) (December 2000). Available from, as of July 13, 2009: http://www.epa.gov/pesticides/biopesticides/ingredients/index_p-s.htm from HSDB</p> <p>Toxicological Information Health Effects Irritation-Eyes, Nose, Throat, Skin---Moderate (HE15); Allergic Contact Dermatitis (HE3) from OSHA Chemical Sampling Information</p> <p>Symptoms Irritation of eyes, skin, nose, throat; skin rash, itching; anaphylaxis (one case); INGES. ACUTE: Sore throat from OSHA Chemical Sampling Information</p> <p>Target Organs Eyes, skin, respiratory system from OSHA Chemical Sampling Information</p> <p>https://www.ewg.org/guides/substances/1258-CINNAMAL#.W4SOauhKiUk</p>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p>Recognized by the European Union as a skin allergen Allergen list - EU Cosmetics Directive</p> <p>The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p> <p>https://cosmeticsinfo.org/ingredient/cinnamal-0</p> <p>The Food and Drug Administration (FDA) includes Cinnamal on its list of substances considered Generally Recognized As Safe (GRAS) for use as a synthetic flavoring substance. The safety of Cinnamal has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established. The IFRA Standard restricts the use of Cinnamal in fragrances because it of potential sensitization.</p> <p>More safety Information: Link to FDA Code of Federal Regulations for Cinnamal: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=182.60&SearchTerm=cinnamaldehyde</p> <p>The Joint FAO/WHO Expert Committee on Food Additives (JECFA) concluded that Cinnamal does not present a safety concern at current levels of intake when used as a flavoring agent.</p> <p>Link to the JECFA safety evaluation of Cinnamal: http://www.inchem.org/documents/jecfa/jecval/jec_418.htm</p> <p>The Flavor and Extract Manufacturers Association Expert Panel has reviewed the safety of Cinnamal and determined that it was Generally Recognized as Safe (GRAS) for use a flavoring substance. In Europe, Cinnamal is included on the list of "allergenic" substances. The European Cosmetics Regulation requires manufacturers of cosmetics and personal care products to indicate the presence of certain "allergenic" substances in the list of ingredients if they are present above certain levels in the product (see Annex III). The presence of Cinnamal must be indicated in the list of ingredients when its concentration exceeds: 0.001% in leave-on the skin products 0.01% in products that are rinsed off the skin.</p> <p>Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013</p> <p>http://www.thegoodscentscompany.com/data/rw1002632.html#tosafy</p> <p>European information : Most important hazard(s): Xn - Harmful. R 21/41 - Harmful in contact with skin, risk of serious damage to eyes. R 38 - Irritating to skin. R 43 - May cause sensitisation by skin contact. S 02 - Keep out of the reach of children. S 24 - Avoid contact with skin.</p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) Skin irritation (Category 2), H315 Skin sensitisation (Category 1), H317</p>
Cinnamyl Alcohol (3-Phenyl-2-propen-1-ol)	Y	Y	<p>https://chem.nlm.nih.gov/chemidplus/rn/104-54-1 <i>Skin/eye irritant</i></p> <p>https://pubchem.ncbi.nlm.nih.gov/compound/5315892#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements</p>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p>H317 (96.97%): May cause an allergic skin reaction [Warning Sensitization, Skin]</p> <p>https://cosmeticsinfo.org/ingredient/cinnamyl-alcohol-0</p> <p>The Food and Drug Administration (FDA) includes Cinnamyl Alcohol on its list of flavoring agents permitted for direct addition to food. The safety of Cinnamyl Alcohol has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established. The IFRA Standard restricts the use of Cinnamyl in fragrances because of potential sensitization.</p> <p>More safety Information: Link to FDA Code of Federal Regulations for Cinnamyl Alcohol: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.515&SearchTerm=cinnamyl%20alcohol</p> <p>The Joint FAO/WHO Expert Committee on Food Additives (JECFA) concluded that Cinnamyl Alcohol does not present a safety concern at current levels of intake when used as a flavoring agent.</p> <p>Link to the JECFA safety evaluation of Cinnamyl Alcohol: http://www.inchem.org/documents/jecfa/jecval/jec_422.htm</p> <p>The Flavor and Extract Manufacturers Association Expert Panel has reviewed the safety of Cinnamyl Alcohol and determined that it was Generally Recognized as Safe (GRAS) for use as a flavoring substance. In Europe, Cinnamyl Alcohol is included on the list of "allergenic" substances. The European Cosmetics Regulation requires manufacturers of cosmetics and personal care products to indicate the presence of certain "allergenic" substances in the list of ingredients if they are present above certain levels in the product (see Annex III). The presence of Cinnamyl Alcohol must be indicated in the list of ingredients when its concentration exceeds: 0.001% in leave-on the skin products 0.01% in products that are rinsed off the skin.</p> <p>Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013</p> <p>http://www.thegoodscentscompany.com/data/rw1003292.html#tosafety</p> <p>European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 36/38 - Irritating to skin and eyes.</i> <i>R 43 - May cause sensitisation by skin contact.</i> <i>S 24 - Avoid contact with skin.</i></p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i> <i>Skin sensitisation (Category 1), H317</i></p>
Citral (Geranial)	Y		<p>https://chem.nlm.nih.gov/chemidplus/rn/5392-40-5 <i>Skin/eye irritant</i></p> <p>https://pubchem.ncbi.nlm.nih.gov/compound/638011#section=Hazards-Identification Signal: Danger GHS Hazard Statements <i>H315 (100%): Causes skin irritation [Warning Skin corrosion/irritation]</i> <i>H317 (23.56%): May cause an allergic skin reaction [Warning Sensitization, Skin]</i></p> <p>Health Hazard</p>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

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Chemical	Baby Powder	Shower-to-Shower																																														
			<p>SYMPTOMS: Symptoms of exposure to this compound may include contact dermatitis. ACUTE/CHRONIC HAZARDS: This compound is a local irritant. When heated to decomposition it emits acrid smoke and fumes. (NTP, 1992) from CAMEO Chemicals</p> <p>Skin, Eye, and Respiratory Irritations</p> <p>Irritant effect of 19 oils & 20 synthetic perfumes used in cosmetics were tested on skin of 50 male volunteers. Citral @ 32% concn was the most irritating of perfumes in human patch test. Motoyoshi k et al; Cosmet Toilet 94: 41 (197) from HSDB</p> <p>Irritating to skin. European Chemicals Bureau; IUCLID Dataset, Citral (CAS No. 5392-40-5). Available from, as of January 22, 2007: http://esis.jrc.ec.europa.eu/ from HSDB</p> <p>A cumulative irritation study was carried out on 8 volunteers. Patches were placed on the back daily, removed at 24 hr and read and then replaced with a fresh patch, over a period of 21 days. /Citral concentrations tested included 1, 4 and 8% in petrolatum./ The 8 % concentration was found to be a marginal irritant. European Chemicals Bureau; IUCLID Dataset, Citral (CAS No. 5392-40-5). Available from, as of January 22, 2007: http://esis.jrc.ec.europa.eu/ from HSDB</p> <p>During an investigation of an outbreak of dermatitis following the introduction of a lemon-scented detergent, citral was shown by patch tests to be a strong primary irritant if applied in association with heat; 10% citral induced slight responses at 23 deg C and pronounced responses at 43 deg C. Abstract: PubMed Rothenborg HW et al; Contact Dermatitis 3 (1): 37 (1977) from HSDB</p> <p>NIOSH Toxicity Data</p> <table><tr><th>Measurement</th><th>Date</th><th>System</th><th>Route/Organism</th><th>Dose</th><th>Effect</th></tr><tr><td>Skin and Eye Irritation</td><td>October 2017</td><td></td><td>skin /guinea pig</td><td>1%/48H</td><td>moderate</td></tr><tr><td>Skin and Eye Irritation</td><td>October 2017</td><td></td><td>skin /guinea pig</td><td>100 mg/24H</td><td>severe</td></tr><tr><td>Skin and Eye Irritation</td><td>October 2017</td><td></td><td>skin /human</td><td>2%/2D</td><td></td></tr><tr><td>Skin and Eye Irritation</td><td>October 2017</td><td></td><td>skin /human</td><td>40 mg/24H</td><td>mild</td></tr><tr><td>Skin and Eye Irritation</td><td>October 2017</td><td></td><td>skin /man</td><td>16 mg/48H</td><td>severe</td></tr><tr><td>Skin and Eye Irritation</td><td>October 2017</td><td></td><td>skin /pig</td><td>50 mg/48H</td><td>severe</td></tr></table>				Measurement	Date	System	Route/Organism	Dose	Effect	Skin and Eye Irritation	October 2017		skin /guinea pig	1%/48H	moderate	Skin and Eye Irritation	October 2017		skin /guinea pig	100 mg/24H	severe	Skin and Eye Irritation	October 2017		skin /human	2%/2D		Skin and Eye Irritation	October 2017		skin /human	40 mg/24H	mild	Skin and Eye Irritation	October 2017		skin /man	16 mg/48H	severe	Skin and Eye Irritation	October 2017		skin /pig	50 mg/48H	severe
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Ingredient List – Johnson's Baby Powder & Shower-to-Shower

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Chemical	Baby Powder	Shower-to-Shower																							
			<table><tr><td>Skin and Eye Irritation</td><td>October 2017</td><td></td><td>skin /rabbit</td><td>500 mg/24H</td><td>moderate</td></tr><tr><td>Skin and Eye Irritation</td><td>October 2017</td><td></td><td>skin /rabbit</td><td>100 mg/24H</td><td>severe</td></tr><tr><td>Skin and Eye Irritation</td><td>October 2017</td><td></td><td>skin /woman</td><td>2%</td><td></td></tr></table>					Skin and Eye Irritation	October 2017		skin /rabbit	500 mg/24H	moderate	Skin and Eye Irritation	October 2017		skin /rabbit	100 mg/24H	severe	Skin and Eye Irritation	October 2017		skin /woman	2%	
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Skin and Eye Irritation	October 2017		skin /woman	2%																					
			<p>Skin Symptoms</p> <p>Redness.</p> <p>from ILO-ICSC</p> <p>Toxicity Summary</p> <p>Citral was rapidly absorbed from the gastro -intestinal tract. Much of an applied dermal dose was lost due to its extreme volatility, but the citral remaining on the skin was fairly well absorbed. Citral was rapidly metabolized and excreted as metabolites. Urine was the major route of elimination. Acute toxicity of this chemical is low in rodents because the oral or dermal LD50 values were more than 1000 mg/kg. This chemical is irritating to skin and not irritating to eyes in rabbits. There is some evidence that this chemical is a human skin sensitizer.</p> <p>OECD; Screening Information Data Set for Citral, CAS # 5392-40-5 (2004). Available from, as of January 22, 2007: http://www.inchem.org/pages/sids.html</p> <p>https://www.ewg.org/guides/substances/1279-CITRAL#.W4SeRehKiUk</p> <p>Recognized by the European Union as a skin allergen Allergen list - EU Cosmetics Directive</p> <p>The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p> <p>https://cosmeticsinfo.org/ingredient/citral-0</p> <p>The Food and Drug Administration (FDA) includes Citral in its list of substances considered Generally Recognized As Safe (GRAS) as a synthetic flavoring substance. The safety of Citral has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established. The IFRA Standard restricts the use of Citral in fragrances because of potential sensitization.</p> <p>More safety Information:</p> <p>Link to FDA Code of Federal Regulations for Citral: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=182.60&SearchTerm=citral</p> <p>The Joint FAO/WHO Expert Committee on Food Additives (JECFA) established an Acceptable Daily Intake of up to 0.5 mg/kg body weight Citral when used as a flavoring agent.</p> <p>Link to the JECFA safety evaluation of Citral: http://www.inchem.org/documents/jecfa/jecval/jec_432.htm</p> <p>The Flavor and Extract Manufacturers Association Expert Panel has reviewed the safety of Citral and determined that it is Generally Recognized as Safe (GRAS) for use as a flavoring substance. In Europe, Citral is included on the list of "allergenic" substances. The European Cosmetics Regulation requires manufacturers of cosmetics and personal care products to indicate the presence of certain "allergenic" substances in the list of ingredients if they are present above certain levels in the product (see Annex III). The presence of</p>																						

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p>Citral must be indicated in the list of ingredients when its concentration exceeds: 0.001% in leave-on the skin products 0.01% in products that are rinsed off the skin.</p> <p>Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013</p> <p>http://www.thegoodscentscompany.com/data/rw1003432.html#tosaftey</p> <p>European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 38 - Irritating to skin.</i> <i>R 43 - May cause sensitisation by skin contact.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i></p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i> <i>Skin sensitisation (Category 1), H317</i></p>
Citronellyl Nitrile (3,7-Dimethyloct-6-enenitrile)		Y	<p>http://www.thegoodscentscompany.com/data/rw1008932.html#tosaftey</p> <p>European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 36/38 - Irritating to skin and eyes.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i></p>
Citrus Aurantifolia (Lime) Oil	Y		<p>https://chem.nlm.nih.gov/chemidplus/rn/8008-26-2 <i>Skin/eye irritant (Lime Oil)</i></p> <p>https://chem.nlm.nih.gov/chemidplus/rn/90063-52-8 (Citrus Aurantifolia Extract)</p>
Commiphora Myrrha Oil		Y	<p>http://www.thegoodscentscompany.com/data/es1002061.html#tosaftey</p> <p>European information : Most important hazard(s): <i>Xn - Harmful.</i> <i>R 36/38 - Irritating to skin and eyes.</i></p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i> <i>Skin sensitisation (Category 1), H317</i></p>
Commiphora Myrrha Resin	Y		<p>http://www.thegoodscentscompany.com/data/rs1008771.html</p> <p>European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 36/38 - Irritating to skin and eyes.</i></p>
Coriandrum Sativum (Coriander) Fruit Oil (Cilantro)	Y		<p>https://chem.nlm.nih.gov/chemidplus/rn/startswith/8008-52-4 <i>Skin/eye irritant</i></p> <p>https://www.ewg.org/guides/substances/1504-CORIANDRUMSATIVUMCORIANDEROIL#.W37RTehKiUk Component: LINALOOL Recognized by the European Union as a skin allergen. Allergen list - EU Cosmetics Directive</p> <p>Component: LINALOOL</p>

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p>The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p> <p>Component: GERANIOL Recognized by the European Union as a skin allergen Allergen list - EU Cosmetics Directive</p> <p>Component: GERANIOL The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p> <p>Component: LINALOOL This peer-reviewed study reports this substance is a significant skin sensitizer after oxidation. Johanna Bråred Christensson, Mihály Matura, Birgitta Gruvberger, Magnus Bruze & Ann-Therese Karlberg. 2010. Linalool--a significant contact sensitizer after air exposure. Contact dermatitis 62(1), 32-41.</p> <p>Component: LINALOOL This peer-reviewed study reports this substance is a significant skin sensitizer after oxidation. Johanna Bråred Christensson, Pia Forsström, Ann-Marie Wennberg, Ann-Therese Karlberg & Mihály Matura. 2009. Air oxidation increases skin irritation from fragrance terpenes. Contact dermatitis 60(1), 32-40.</p> <p>Component: LINALOOL This peer-reviewed study reports this substance is a significant skin sensitizer after oxidation. Deirdre A. Buckley. 2011. Allergy to oxidized linalool in the UK. Contact dermatitis 64(4), 240-1.</p> <p>Component: LINALOOL This peer-reviewed study reports this substance is a contact skin allergen. Mihály Matura, Ian R. White, Cecilia Svedman, Jeanne D. Johansen, An Goossens, Peter Frosch, Magnus Bruze, Klaus E. Andersen, Anna Börje, Maria Sköld & Ann-Therese Karlberg. 2005. Selected oxidized fragrance terpenes are common contact allergens. Contact dermatitis 52(6), 320-8.</p> <p>Component: D-LIMONENE Recognized by the European Union as a skin allergen Allergen list - EU Cosmetics Directive</p> <p>http://www.thegoodscentscompany.com/data/es1003771.html#tosafy European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 36/37/38 - Irritating to eyes, respiratory system, and skin.</i> <i>R 43 - May cause sensitisation by skin contact.</i></p>
Coumarin	Y	Y	<p>https://pubchem.ncbi.nlm.nih.gov/compound/323#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements <i>H317 (90.48%): May cause an allergic skin reaction [Warning Sensitization, Skin]</i></p> <p>NIOSH Toxicity Data</p>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower								
				Measurement	System	Route/Organism	Dose	Effect	Date	
				Skin and Eye Irritation		skin /human	5%/2D		June 2017	
				Skin and Eye Irritation		skin /man	5%		June 2017	
			<p>Skin Symptoms</p> <p>MAY BE ABSORBED! Redness. Pain. from ILO-ICSC</p> <p>https://www.ewg.org/guides/substances/1528-COUMARIN#.W37OeehKiUk Recognized by the European Union as a skin allergen. Allergen list - EU Cosmetics Directive</p> <p>The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p> <p>http://www.thegoodscentscompany.com/data/rw1003832.html#tosaftey European information : Most important hazard(s): Xn - Harmful. R 43 - May cause sensitisation by skin contact. S 24/25 - Avoid contact with skin and eyes.</p> <p>https://cosmeticsinfo.org/ingredient/coumarin-0 The Food and Drug Administration (FDA) does not permit Coumarin to be directly added to food. The safety of Coumarin has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established. The IFRA Standard restricts the use of Coumarin in fragrances because of potential sensitization.</p> <p>In 2008, the International Fragrance Association (IFRA) issued a position statement that states that the fragrance industry is not aware of any reported systemic adverse health effects with regard to topically applied Coumarin.</p> <p>More safety Information: Link to the FDA Code of Federal Regulations for Coumarin: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=189.130&SearchTerm=coumarin</p> <p>In Europe, Coumarin is included on the list of "allergenic" substances. The European Cosmetics Directive requires manufacturers of cosmetics and personal care products to indicate the presence of certain "allergenic" substances in the list of ingredients if they are present above certain levels in the product (see Annex III). The presence of Coumarin must be indicated in the list of ingredients when its concentration exceeds: 0.001% in leave-on the skin products 0.01% in products that are rinsed off the skin</p> <p>Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013</p>							

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p>The European Commission's Scientific Committee on Consumer Products (SCCP) evaluated Coumarin as a fragrance allergen and concluded that this ingredient was frequently reported and a well-recognized consumer allergen. Link to the European Commission's SCCP opinion concerning Coumarin: http://ec.europa.eu/health/ph_risk/committees/sccp/documents/out98_en.pdf</p> <p>Coumarin was evaluated by IARC and was not classifiable as to its carcinogenicity in humans.</p> <p>Link to the IARC monograph for Coumarin: https://monographs.iarc.fr/wp-content/uploads/2018/06/mono77-9.pdf https://monographs.iarc.fr/preamble-to-the-iarc-monographs-amended-january-2006/preamble-to-the-iarc-monographs-13/</p>
Cuminum Cyminum (Cumin) Seed Oil (Cumin Oil)	Y		<p>https://chem.nlm.nih.gov/chemidplus/rn/startswith/8014-13-9 Skin/eye irritant</p> <p>http://www.thegoodscentscompany.com/data/es1016101.html#tosaftey European information : Most important hazard(s): Xn - Harmful. R 36/37/38 - Irritating to eyes, respiratory system, and skin.</p>
Cyclamen Aldehyde	Y	Y	<p>https://chem.nlm.nih.gov/chemidplus/rn/startswith/103-95-7 Skin/eye irritant</p> <p>https://www.ewg.org/guides/substances/1563-CYCLAMENALDEHYDE#.W37KcehKiUk The European Commission's Scientific Committee on Consumer Safety reports this substance lacks data on contact allergy in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p> <p>http://www.thegoodscentscompany.com/data/rw1004112.html European information : Most important hazard(s): Xi N - Irritant, Dangerous for the environment. R 38 - Irritating to skin.</p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) Skin irritation (Category 2), H315</p>
Decanal	Y		<p>https://pubchem.ncbi.nlm.nih.gov/compound/8175#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements</p> <p>H315 (25.17%): Causes skin irritation [Warning Skin corrosion/irritation]</p> <p>Health Hazard On direct contact can produce eye and skin irritation; low general toxicity. (USCG, 1999) from CAMEO Chemicals</p> <p>https://chem.nlm.nih.gov/chemidplus/rn/startswith/112-31-2 Skin/eye irritant</p> <p>https://www.ewg.org/guides/substances/1689-DECANAL#.W37It-hKiUk The European Commission's Scientific Committee on Consumer Safety reports this substance lacks data on contact allergy in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower																					
Chemical	Baby Powder	Shower-to-Shower																			
			<p>http://www.thegoodscentscompany.com/data/rw1000172.html#tosafte</p> <p>European information : Most important hazard(s): <i>Xi N - Irritant, Dangerous for the environment.</i> <i>R 38 - Irritating to skin.</i></p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i></p>																		
Diethyl Phthalate		Y	<p>https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PR758.pdf https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PRN475.pdf https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr200.pdf</p> <p>https://pubchem.ncbi.nlm.nih.gov/compound/6781#section=Hazards-Identification</p> <p>Signal: Danger GHS Hazard Statements <i>H315 (22.62%): Causes skin irritation [Warning Skin corrosion/irritation]</i></p> <p>Skin, Eye, and Respiratory Irritations <i>DEP is slightly irritating to the eye and skin.</i> Bingham, E.; Cohrssen, B.; Powell, C.H.; Patty's Toxicology Volumes 1-9 5th ed. John Wiley & Sons. New York, N.Y. (2001)., p. V6 824 from HSDB</p> <p>NIOSH Toxicity Data</p> <table><tr><th>Measurement</th><th>System</th><th>Route/Organism</th><th>Dose</th><th>Effect</th><th>Date</th></tr><tr><td>Skin and Eye Irritation</td><td></td><td>eye /rabbit</td><td>112 mg</td><td></td><td>October 2017</td></tr><tr><td>Skin and Eye Irritation</td><td></td><td>skin /human</td><td>2%/3W- intermittent</td><td>mild</td><td>October 2017</td></tr></table> <p>https://chem.nlm.nih.gov/chemidplus/rn/startswith/84-66-2 Skin/eye irritant</p> <p>https://cosmeticsinfo.org/ingredient/dimethyl-phthalate-diethyl-phthalate-and-dibutyl-phthalate-0</p> <p>More safety Information: The U.S. Food and Drug Administration(FDA) has stated that, at the present time, it does not have evidence that phthalates as used in cosmetics pose a safety risk. FDA noted that an expert panel convened from 1998 to 2000 by the National Toxicology Program (NTP), headquartered at the National Institute of Environmental Health Sciences (NIEHS), concluded that reproductive risks from exposure to phthalates from all sources were minimal to negligible in most cases.</p> <p>FDA has reviewed all of the available safety and toxicity data for phthalates, including biomonitoring data from the Centers for Disease Control (CDC) measuring levels in human urine, as well as the CIR conclusions based on reviews in 1985 and 2002. None of the data reviewed by FDA established an association between the use of phthalates in cosmetic products and a health risk.</p>	Measurement	System	Route/Organism	Dose	Effect	Date	Skin and Eye Irritation		eye /rabbit	112 mg		October 2017	Skin and Eye Irritation		skin /human	2%/3W- intermittent	mild	October 2017
Measurement	System	Route/Organism	Dose	Effect	Date																
Skin and Eye Irritation		eye /rabbit	112 mg		October 2017																
Skin and Eye Irritation		skin /human	2%/3W- intermittent	mild	October 2017																

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			<p>Based on this information, FDA determined that there wasn’t a sound, scientific basis to support taking regulatory action against cosmetics containing phthalates.</p> <p>https://www.fda.gov/Cosmetics/ProductsIngredients/Ingredients/ucm128250.htm</p> <p>FDA includes Dimethyl Phthalate (DMP), Diethyl Phthalate (DEP) and Dibutyl phthalate (DBP) on its list of indirect food additives. For example, all three ingredients may be used in adhesives that contact food, DEP and DBP may be used in food contact polymers, and DBP may be used as a slimicide in paper and paperboard used for food packaging.</p> <p>DMP and DEP may be used in cosmetics and personal care products marketed in Europe according to the general provisions of the Cosmetics Regulation of the European Union . DBP is not permitted for use in cosmetics and personal care products in the European Union (see Annex II).</p> <p>DBP was banned in Europe because all substances classified as carcinogenic, mutagenic or toxic to reproduction (categories 1 and 2) under EU chemical hazard classification legislation are automatically banned from use in cosmetics and personal care products, regardless of use concentration. The low exposure to DBP in cosmetics and personal care products was not considered when this ban went into effect. As mentioned earlier, the CIR Expert Panel estimated that exposure to DBP from using cosmetic and personal care products would be well below the dose that did not cause any reproductive and developmental effects in animals. Therefore, the CIR Expert Panel did not see the need to change their original conclusion that DBP was safe as used in cosmetic products.</p> <p>Similar, when considering exposure European experts, (SCCNFP) agree with CIR and concluded in their 2002 opinion that "the safety profile of diethyl phthalate supports its use in cosmetic products at current levels." This opinion was confirmed in a second opinion in 2004.</p> <p>Learn more about EU Cosmetic Regulation: http://ec.europa.eu/growth/tools-databases/cosing/</p> <p>Learn more about SCCNFP’s 2004 opinion on Dibutyl phthalate: http://ec.europa.eu/health/ph_risk/committees/sccp/documents/out287_en.pdf</p> <p>It’s a myth that phthalates are ‘hidden’ in fragrances</p> <p>Fragrances are usually composed of numerous individual substances that are blended together to achieve the desired scent. If a cosmetic product contains a fragrance, this is labelled using the word 'fragrance' or 'parfum' in the ingredients list rather than having to list out all of the individual components. This is legally allowed by the strict cosmetic safety laws and is common practice around the world.</p> <p>It is, however, not a way of ‘hiding’ ingredients as is sometimes, wrongly, claimed. All of the ingredients that make up the fragrance are still assessed very carefully as part of the overall product safety assessment. DEP and DMP may legally and safely be used as part of the fragrance mix. No substances banned from use as cosmetic ingredients are allowed to be used as components of cosmetic fragrances.</p> <p>Can phthalates be used in personal care products intended for use by children?</p> <p>Phthalate ingredients can be used in personal care products intended for use by children - e.g., in lotions, shampoos, etc. Like personal care products intended for use by adults, the only phthalate that is sometimes present in personal care products intended for children and infants is DEP. The safety of DEP is well accepted among the scientific community. To date, all scientific reviews around the world by key scientific experts and governmental agencies have concluded that DEP is safe for use in cosmetics and personal care products under the current conditions of use. DEP has been reviewed by the U.S. Cosmetic Ingredient Review (CIR) Expert Panel and the European Commission's independent scientific expert committee (the Scientific Committee on Consumer Safety, SCCS and formerly known as the</p>

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower																											
Chemical	Baby Powder	Shower-to-Shower																									
			<p>SCCNFP). Both expert scientific groups have approved the safe use of DEP in cosmetic products and have not deemed it necessary to impose any specific warnings or restrictions for its use.</p> <p>http://www.thegoodscentscompany.com/data/rw1004351.html#tosafy</p> <p>European information : Most important hazard(s): <i>Xn - Harmful.</i> <i>R 36/37/38 - Irritating to eyes, respiratory system, and skin.</i></p>																								
Dihydrocitronellol (3,7-Dimethyloctan-1-ol)		Y	<p>https://pubchem.ncbi.nlm.nih.gov/compound/7792#section=GHS-Classification</p> <p>Signal: Warning GHS Hazard Statements</p> <p><i>H315 (100%): Causes skin irritation [Warning Skin corrosion/irritation]</i></p> <p>https://chem.nlm.nih.gov/chemidplus/rn/startswith/106-21-8</p> <p><i>Skin/eye irritant</i></p> <p>http://www.thegoodscentscompany.com/data/rw1000592.html#tosafy</p> <p>European information : Most important hazard(s): <i>Xi N - Irritant, Dangerous for the environment.</i> <i>R 36/38 - Irritating to skin and eyes.</i></p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i></p>																								
Dimethylhydroquinone (1,4-Dimethoxybenzene)	Y		<p>https://chem.nlm.nih.gov/chemidplus/rn/startswith/150-78-7</p> <p><i>Skin/eye irritant</i></p> <p>https://pubchem.ncbi.nlm.nih.gov/compound/9016#section=GHS-Classification</p> <p>Signal: Warning GHS Hazard Statements</p> <p><i>H315 (100%): Causes skin irritation [Warning Skin corrosion/irritation]</i></p> <p>NIOSH Toxicity Data</p> <table><tr><th>Measurement</th><th>System</th><th>Route/Organism</th><th>Dose</th><th>Effect</th><th>Date</th></tr><tr><td>Skin and Eye Irritation</td><td></td><td>skin /guinea pig</td><td>40%/24H</td><td>moderate</td><td>April 2015</td></tr><tr><td>Skin and Eye Irritation</td><td></td><td>skin /rabbit</td><td>6 gm/12D- intermittent</td><td>mild</td><td>April 2015</td></tr><tr><td>Skin and Eye Irritation</td><td></td><td>skin /rabbit</td><td>500 mg/24H</td><td>moderate</td><td>April 2015</td></tr></table> <p>http://www.thegoodscentscompany.com/data/rw1004451.html#tosafy</p>	Measurement	System	Route/Organism	Dose	Effect	Date	Skin and Eye Irritation		skin /guinea pig	40%/24H	moderate	April 2015	Skin and Eye Irritation		skin /rabbit	6 gm/12D- intermittent	mild	April 2015	Skin and Eye Irritation		skin /rabbit	500 mg/24H	moderate	April 2015
Measurement	System	Route/Organism	Dose	Effect	Date																						
Skin and Eye Irritation		skin /guinea pig	40%/24H	moderate	April 2015																						
Skin and Eye Irritation		skin /rabbit	6 gm/12D- intermittent	mild	April 2015																						
Skin and Eye Irritation		skin /rabbit	500 mg/24H	moderate	April 2015																						

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p>European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 36/38 - Irritating to skin and eyes.</i></p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i></p>
Ethyl 3-methyl-3-phenyloxirane-2-carboxylate (Ethyl Methylphenylglycidate)	Y		<p>https://pubchem.ncbi.nlm.nih.gov/compound/6501#section=Hazards-Identification Signal: Warning GHS Hazard Statements <i>H317 (77.27%): May cause an allergic skin reaction [Warning Sensitization, Skin]</i></p> <p>http://www.thegoodscentscompany.com/data/rw1001602.html#tosaftey European information : GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i></p>
Ethyl Benzoate	Y		<p>https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr578.pdf https://pubchem.ncbi.nlm.nih.gov/compound/7165#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements <i>H315 (72.29%): Causes skin irritation [Warning Skin corrosion/irritation]</i></p> <p>https://cosmeticsinfo.org/ingredient/ethyl-benzoate The Food and Drug Administration (FDA) permits Methyl Benzoate, Ethyl Benzoate, Propyl Benzoate, Isopropyl Benzoate and Isobutyl Benzoate to be used as flavoring agents for direct addition to food. Butyl Benzoate is permitted for use as an indirect food additive as a component of adhesives.</p> <p>https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.515&SearchTerm=benzyl%20benzoate https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=175.105</p> <p>The European Union lists salts and esters of benzoic acid (including Methyl Benzoate, Ethyl Benzoate, Propyl Benzoate, Butyl Benzoate, Isopropyl Benzoate and Isobutyl Benzoate) as preservatives that may be safely used in cosmetics at concentrations up to 0.5% (See Annex IV).</p> <p>Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013</p> <p>http://www.thegoodscentscompany.com/data/rw1004771.html#tosaftey European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 36/38 - Irritating to skin and eyes.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i></p>
Ethyl heptoate	Y		<p>http://www.thegoodscentscompany.com/data/rw1009172.html#tosaftey European information : Most important hazard(s):</p>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			<p><i>Xi - Irritant</i> <i>R 36/38 - Irritating to skin and eyes.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i></p>
Ethyl Vanillin	Y		<p>https://pubchem.ncbi.nlm.nih.gov/compound/8467#section=GHS-Classification Signal: Warning GHS Hazard Statements <i>H315 (14.69%): Causes skin irritation [Warning Skin corrosion/irritation]</i></p> <p>Health Hazard ACUTE/CHRONIC HAZARDS: Toxic. May cause irritation on contact. (NTP, 1992) from CAMEO Chemicals</p> <p>Skin, Eye, and Respiratory Irritations <i>A human skin irritant.</i> Lewis, R.J. Sax's Dangerous Properties of Industrial Materials. 9th ed. Volumes 1-3. New York, NY: Van Nostrand Reinhold, 1996., p. 1610 from HSDB</p> <p>Toxicity Summary HUMAN EXPOSURE AND TOXICITY: Research in humans showed that ethyl vanillin had no significant effect on the activity of five human CYP450 enzymes with concentration ranged from 8 to 128 uM. A 2% concentration of ethyl vanillin caused mild irritation on the skin of humans after 48 hours of direct contact. ANIMAL STUDIES from HSDB</p> <p>https://chem.nlm.nih.gov/chemidplus/rn/startswith/121-32-4 Skin/eye irritant</p> <p>https://www.ewg.org/guides/substances/2100-ETHYLVANILLIN#.W33GAehKiUk The European Commission's Scientific Committee on Consumer Safety reports this substance shows some evidence of causing contact allergy in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p> <p>http://www.thegoodscentscompany.com/data/rw1002652.html#tosafty European information : Most important hazard(s): Xn - Harmful. <i>R 36/37/38 - Irritating to eyes, respiratory system, and skin.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i></p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i></p>
Eugenol	Y	Y	<p>https://pubchem.ncbi.nlm.nih.gov/compound/3314#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements</p> <p><i>H317 (99.88%): May cause an allergic skin reaction [Warning Sensitization, Skin]</i></p> <p>Health Hazard</p>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p>SYMPTOMS: <i>This compound is a primary irritant and sensitizer and can cause contact dermatitis. Irritation of the skin, eyes and respiratory tract occurs.</i> Skin contact may cause an inflammatory reaction on the skin. Prolonged or repeated skin contact may cause allergic dermatitis.. Skin sensitization may also occur. (NTP, 1992) from CAMEO Chemicals</p> <p>https://chem.nlm.nih.gov/chemidplus/rn/startswith/97-53-0 <i>Skin/eye irritant</i></p> <p>https://cosmeticsinfo.org/ingredient/eugenol-0 The Food and Drug Administration (FDA) includes clove and its derivatives, including Eugenol, on its list of substances affirmed as Generally Recognized As Safe (GRAS) as direct food substances. The safety of Eugenol has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established. The IFRA Standard restricts the use of Eugenol in fragrances because of potential sensitization.</p> <p>More safety Information: Link to FDA Code of Federal Regulations for Eugenol: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=184.1257&SearchTerm=eugenol</p> <p>The Joint FAO/WHO Expert Committee on Food Additives (JECFA) established an Acceptable Daily Intake for Eugenol of up to 2.5 mg/kg body weight when used as a flavoring agent.</p> <p>Link to the JECFA safety evaluation of Eugenol: http://www.inchem.org/documents/jecfa/jecval/jec_841.htm</p> <p>The Flavor and Extract Manufacturers Association Expert Panel has reviewed the safety of Eugenol and determined that it is Generally Recognized as Safe (GRAS) for use as a flavoring agent. In Europe, Eugenol is included on the list of "allergenic" substances. The European Cosmetics Regulation requires manufacturers of cosmetics and personal care products to indicate the presence of certain "allergenic" substances in the list of ingredients if they are present above certain levels in the product (see Annex III). The presence of Eugenol must be indicated in the list of ingredients when its concentration exceeds: 0.001% in leave-on the skin products 0.01% in products that are rinsed off the skin.</p> <p>Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013</p> <p>http://www.thegoodscentscompany.com/data/rw1004992.html#tosafy European information : Most important hazard(s): Xn - Harmful. R 36/37/38 - Irritating to eyes, respiratory system, and skin. R 42/43 - May cause sensitization by inhalation and skin contact.</p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin sensitization (Category 1), H317</i></p>
Formic acid, phenylmethyl ester (Benzyl formate)	Y		<p>http://www.thegoodscentscompany.com/data/rw1012591.html#tosafy European information : Most important hazard(s): Xn - Harmful. R 21/22 - Harmful in contact with skin and if swallowed. S 24 - Avoid contact with skin.</p>

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) Acute toxicity, Dermal (Category 3), H311
Gamma-Nonalactone (5-Pentyloxolan-2-one)	Y		https://pubchem.ncbi.nlm.nih.gov/compound/7710#section=Hazards-Identification Signal: Warning GHS Hazard Statements <i>H315 (50%): Causes skin irritation [Warning Skin corrosion/irritation]</i> Skin, Eye, and Respiratory Irritations <i>A skin irritant.</i> Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 979 from HSDB https://chem.nlm.nih.gov/chemidplus/rn/startswith/104-61-0 Skin/eye irritant http://www.thegoodscentscompany.com/data/rw1000532.html#tosaftey European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 36/38 - Irritating to skin and eyes.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i>
Gamma-Undecalactone	Y		https://chem.nlm.nih.gov/chemidplus/rn/startswith/104-67-6 Skin/eye irritant https://pubchem.ncbi.nlm.nih.gov/compound/7714#section=GHS-Classification Signal: Warning GHS Hazard Statements <i>H315 (19.3%): Causes skin irritation [Warning Skin corrosion/irritation]</i> ratio from companies that provide hazard codes. Only hazard codes with percentage values above 10% are shown. http://www.thegoodscentscompany.com/data/rw1000822.html#tosaftey GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i>
Geraniol	Y	Y	https://chem.nlm.nih.gov/chemidplus/rn/startswith/106-24-1 Skin/eye irritant https://pubchem.ncbi.nlm.nih.gov/compound/637566#section=Hazards-Identification Signal: Danger GHS Hazard Statements <i>H315 (98.89%): Causes skin irritation [Warning Skin corrosion/irritation]</i> <i>H317 (99.59%): May cause an allergic skin reaction [Warning Sensitization, Skin]</i> Skin, Eye, and Respiratory Irritations

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p><i>A severe human skin irritant.</i> Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 1440 from HSDB</p> <p>https://www.ewg.org/guides/substances/2340-GERANIOL#.W32bDehKiUk Recognized by the European Union as a skin allergen. Allergen list - EU Cosmetics Directive</p> <p>The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p> <p>https://cosmeticsinfo.org/ingredient/geraniol-0 The Food and Drug Administration (FDA) includes Geraniol on its lists of flavoring substance considered Generally Recognized As Safe (GRAS). The safety of Geraniol has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established. The IFRA Standard restricts the use of Geraniol in fragrances because of potential sensitization.</p> <p>More safety Information: Link to FDA Code of Federal Regulations for Geraniol: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=182.60&SearchTerm=geraniol</p> <p>The Joint FAO/WHO Expert Committee on Food Additives (JECFA) concluded that Geraniol does not present a safety concern at current levels of intake when used as a flavoring agent.</p> <p>Link to the JECFA safety evaluation of Geraniol: http://www.inchem.org/documents/jecfa/jecval/jec_898.htm</p> <p>The Flavor and Extract Manufacturers Association Expert Panel has reviewed the safety of Geraniol and determined that it is Generally Recognized as Safe (GRAS) for use as a flavoring substances. In Europe, Geraniol is included on the list of "allergenic" substances. The European Cosmetics Regulation requires manufacturers of cosmetics and personal care products to indicate the presence of certain "allergenic" substances in the list of ingredients if they are present above certain levels in the product (see Annex III). The presence of Geraniol must be indicated in the list of ingredients when its concentration exceeds: 0.001% in leave-on the skin products 0.01% in products that are rinsed off the skin.</p> <p>Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013</p> <p>http://www.thegoodscentscompany.com/data/rw1006992.html#tosaftey European information : Most important hazard(s): Xi - Irritant R 36/38 - Irritating to skin and eyes. R 43 - May cause sensitisation by skin contact. S 24/25 - Avoid contact with skin and eyes..</p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i> <i>Skin sensitisation (Category 1), H317</i></p>
Geranyl Acetate	Y		<p>https://pubchem.ncbi.nlm.nih.gov/compound/1549026#section=Safety-and-Hazards Signal: Warning</p>

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p>GHS Hazard Statements</p> <p>H315 (15.29%): Causes skin irritation [Warning Skin corrosion/irritation] H317 (15.29%): May cause an allergic skin reaction [Warning Sensitization, Skin]</p> <p>Health Hazard SYMPTOMS: Symptoms of exposure to this compound <i>include skin and eye irritation..</i> ACUTE/CHRONIC HAZARDS: This compound can cause eye damage and skin irritation.. (NTP, 1992) from CAMEO Chemicals</p> <p>Skin, Eye, and Respiratory Irritations In human patch test, geraniol @ 32% concn was severely irritating & geranyl acetate mildly irritating. Motoyoski et al; Cosmet Toiletries 94(8): 41 (1979) from HSDB</p> <p>https://chem.nlm.nih.gov/chemidplus/rn/startswith/105-87-3 <i>Skin/eye irritant</i></p> <p>http://www.thegoodscentscompany.com/data/rw1030092.html#tosafy European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 36/38 - Irritating to skin and eyes.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i></p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i></p>
Heliotropine (piperonal)	Y		<p>https://pubchem.ncbi.nlm.nih.gov/compound/8438#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements</p> <p><i>H317 (96.36%): May cause an allergic skin reaction [Warning Sensitization, Skin]</i></p> <p>Health Hazard SYMPTOMS: Symptoms of exposure to this compound may include depression of the central nervous system and local irritation. ACUTE/CHRONIC HAZARDS: This compound is an irritant. (NTP, 1992) from CAMEO Chemicals</p> <p>TSCA Test Submissions Piperonal (CAS # 120-57-0) was evaluated for primary dermal irritation. The test substance was applied to the cuff of 8 guinea pigs (sex and strain not indicated) at a dose range of 0.25-1.0 mg/kg. Strong skin irritation was evident at 24 hours with slight to gross edema and slight to severe erythema. At 48 hours, slight to moderate edema and erythema was found with eschar formation and necrotic area over part or all of the patch. At 1-week and 2-week observation, desquamation and alopecia was evident. EASTMAN KODAK CO; Letter From Eastman Kodak Co To USEPA Submitting Enclosed Material Safety Data Sheet and Toxicity Report on Piperonal with Attachments; 10/22/91; EPA Doc No. 86-920000085; Fiche No. OTS0533448 from HSDB</p>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			https://chem.nlm.nih.gov/chemidplus/rn/startswith/120-57-0 Skin/eye irritant http://www.thegoodscentscompany.com/data/rw1005891.html#tosafy European information : Most important hazard(s): Xi - Irritant R 36/37/38 - Irritating to eyes, respiratory system, and skin. S 24/25 - Avoid contact with skin and eyes. GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i>
Hexamethylindanopyran (Galaxolide)	Y	Y	<i>Galaxolide</i> https://chem.nlm.nih.gov/chemidplus/rn/startswith/1222-05-5 Skin/eye irritant https://www.ewg.org/guides/substances/2-GALAXOLIDE#.W32QNuhKiUk The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive http://www.thegoodscentscompany.com/data/rw1104661.html#tosafy European information : Most important hazard(s): Xi N - Irritant, Dangerous for the environment. R 38 - Irritating to skin. S 24 - Avoid contact with skin.
Hexane, 1-methoxy- (Methyl Hexyl Ether)		Y	http://www.thegoodscentscompany.com/data/rw1017011.html#tosafy European information : Most important hazard(s): Xi - Irritant R 38 - Irritating to skin. S 24/25 - Avoid contact with skin and eyes.
Hexyl caproate (Hexyl Hexanoate)	Y		https://chem.nlm.nih.gov/chemidplus/rn/startswith/6378-65-0 Skin/eye irritant http://www.thegoodscentscompany.com/data/rw1028161.html#tosafy European information : Most important hazard(s): Xi - Irritant R 36/38 - Irritating to skin and eyes. S 24/25 - Avoid contact with skin and eyes.
Hydroxycitronellal	Y		https://pubchem.ncbi.nlm.nih.gov/compound/7888#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements <i>H317 (100%): May cause an allergic skin reaction [Warning Sensitization, Skin]</i>

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p>https://chem.nlm.nih.gov/chemidplus/rn/startswith/107-75-5 Skin/eye irritant</p> <p>https://cosmeticsinfo.org/ingredient/hydroxycitronellal-0 The Food and Drug Administration (FDA) has approved the use of Hydroxycitronellal as a flavoring agent for direct addition to food. The safety of Hydroxycitronellal has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established. The IFRA Standard restricts the use of Hydroxycitronellal in fragrances because of potential sensitization.</p> <p>More safety Information:</p> <p>Link to FDA Code of Federal Regulations for Hydroxycitronellal: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.515&SearchTerm=hydroxycitronellal</p> <p>The Joint FAO/WHO Expert Committee on Food Additives (JECFA) concluded that Hydroxycitronellal does not present a safety concern at current levels of intake when used as a flavoring agent.</p> <p>Link to the JECFA safety evaluation of Hydroxycitronellal: http://www.inchem.org/documents/jecfa/jecval/jec_1076.htm</p> <p>The Flavor and Extract Manufacturers Association Expert Panel has reviewed the safety of Hydroxycitronellal and determined that it was Generally Recognized as Safe for use as a flavoring substance. In Europe, Hydroxycitronellal is included on the list of "allergenic" substances. The European Cosmetics Regulation requires manufacturers of cosmetics and personal care products to indicate the presence of certain "allergenic" substances in the list of ingredients if they are present above certain levels in the product (see Annex III). The presence of Hydroxycitronellal must be indicated in the list of ingredients when its concentration exceeds: 0.001% in leave-on the skin products 0.01% in products that are rinsed off the skin.</p> <p>Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013</p> <p>http://www.thegoodscentscompany.com/data/rw1000972.html#tosaftey European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 36/38 - Irritating to skin and eyes.</i> <i>R 43 - May cause sensitisation by skin contact.</i> <i>S 24 - Avoid contact with skin.</i></p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i> <i>Skin sensitisation (Category 1), H317</i></p>
Isoamyl Acetate	Y		<p>https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr469.pdf</p> <p>https://pubchem.ncbi.nlm.nih.gov/compound/31276#section=Safety-and-Hazards Signal: Danger GHS Hazard Statements <i>H315: Causes skin irritation [Warning Skin corrosion/irritation]</i></p> <p>Health Hazard</p>

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p>VAPOR: Irritating to eyes, nose and throat. If inhaled, will cause nausea, headache or dizziness. LIQUID: Irritating to skin and eyes. Harmful if swallowed. (USCG, 1999) from CAMEO Chemicals</p> <p>https://cosmeticsinfo.org/ingredient/isoamyl-acetate The Food and Drug Administration reviewed the safety of Amyl Acetate and approved its use as an indirect food additive as a component of adhesives.</p> <p>FDA: Link to the Code of Federal Regulations for Amyl Acetate https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=175.105&SearchTerm=amyl%20acetate</p> <p>The use of Amyl Acetate and Isoamyl Acetate are permitted in Europe subject to the general provisions of the Cosmetics Regulation of the European Union.</p> <p>Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013</p> <p>The Joint FAO/WHO Expert Committee on Food Additives has established an Acceptable Daily Intake of 0-3 mg Isoamyl Acetate/kg body weight. No safety concern was indicated at current levels of intake when used as a flavoring agent. http://www.inchem.org/documents/jecfa/jecval/jec_1138.htm</p> <p>http://www.thegoodscentscompany.com/data/rw1006712.html#tosafty European information : Most important hazard(s): Xi - Irritant <i>R 66 - Repeated exposure may cause skin dryness or cracking.</i></p>
Isopropyl Palmitate		Y	<p>https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PR623.pdf https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PRN475.pdf https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr238.pdf</p> <p>https://cosmeticsinfo.org/ingredient/isopropyl-palmitate</p> <p>https://chem.nlm.nih.gov/chemidplus/rn/startswith/142-91-6 Skin/eye irritant</p> <p>http://www.thegoodscentscompany.com/data/rw1019311.html#tosafty European information : Most important hazard(s): <i>S 24/25 - Avoid contact with skin and eyes.</i></p> <p>https://pubchem.ncbi.nlm.nih.gov/compound/8907#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements</p> <p><i>H315 (100%): Causes skin irritation [Warning Skin corrosion/irritation]</i></p> <p>Skin, Eye, and Respiratory Irritations</p>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower																								
Chemical	Baby Powder	Shower-to-Shower																						
			<p>Direct contact may cause mild irritation /of the/ eye. <i>Prolonged or repeated contact /with the skin/ may cause mild irritation...</i> European Commission, ESIS; IUCLID Dataset,Isopropyl Palmitate (142-91-6) p.24 (2000 CD-ROM edition). from HSDB</p> <p><i>A human skin irritant.</i> Lewis, R.J. Sax's Dangerous Properties of Industrial Materials. 9th ed. Volumes 1-3. New York, NY: Van Nostrand Reinhold, 1996., p. 1991 from HSDB</p> <p>NIOSH Toxicity Data</p> <table><tr><th>Measurement</th><th>System</th><th>Route/Organism</th><th>Dose</th><th>Effect</th><th>Date</th></tr><tr><td>Skin and Eye Irritation</td><td></td><td>skin /human</td><td>84 mg/3D- intermittent</td><td>mild</td><td>January 1997</td></tr><tr><td>Skin and Eye Irritation</td><td></td><td>skin /rabbit</td><td>500 mg/24H</td><td>moderate</td><td>January 1997</td></tr></table>				Measurement	System	Route/Organism	Dose	Effect	Date	Skin and Eye Irritation		skin /human	84 mg/3D- intermittent	mild	January 1997	Skin and Eye Irritation		skin /rabbit	500 mg/24H	moderate	January 1997
Measurement	System	Route/Organism	Dose	Effect	Date																			
Skin and Eye Irritation		skin /human	84 mg/3D- intermittent	mild	January 1997																			
Skin and Eye Irritation		skin /rabbit	500 mg/24H	moderate	January 1997																			
Juniperus Communis Fruit Oil	Y		<p>https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr328.pdf</p> <p>https://www.ewg.org/guides/substances/10468-JUNIPERUSCOMMUNISFRUITOIL#.W31_sehKiUk Component: D-LIMONENE Recognized by the European Union as a skin allergen. Allergen list - EU Cosmetics Directive</p> <p>https://chem.nlm.nih.gov/chemidplus/number/startswith/8012-91-7 <i>Skin/eye irritant</i></p> <p>https://cosmeticsinfo.org/ingredient/juniperus-communis-fruit-extract The Food and Drug Administration (FDA) includes Juniperus communis berry oil on its list of essential oils considered Generally Recognized As Safe (GRAS) as food for human consumption. Juniper tar is approved for use as an analgesic, anesthetic, and antipruritic active ingredient in Over-The-Counter (OTC) anorectal drug products.</p> <p>Link to FDA Code of Federal Regulations for Juniper berry oil and Juniper Tar</p> <p>https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=182.20&SearchTerm=juniperus https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=346.16&SearchTerm=juniper%20tar</p> <p>Juniper Extracts and Juniper Tar may be used in cosmetics and personal care products marketed in Europe according to the general provisions of the Cosmetics Regulation of the European Union.</p> <p>Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013</p> <p>http://www.thegoodscentcompany.com/data/es1029741.html European information : Most important hazard(s): <i>R 38 - Irritating to skin.</i></p>																					

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p><i>R 43 - May cause sensitisation by skin contact.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i></p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i></p>
Lavandula Angustifolia (Lavender) Oil	Y		<p>https://chem.nlm.nih.gov/chemidplus/rn/startswith/8000-28-0 Skin/eye irritant</p> <p>https://www.ewg.org/guides/substances/3172-LAVANDULAANGUSTIFOLIALAVENDER#.W319L-hKiUk Component: LINALOOL Recognized by the European Union as a skin allergen. Allergen list - EU Cosmetics Directive</p> <p>Component: LINALOOL The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p> <p>Component: LINALYL ACETATE The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p> <p>Component: GERANIOL Recognized by the European Union as a skin allergen Allergen list - EU Cosmetics Directive</p> <p>Component: GERANIOL The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p> <p>Component: LINALOOL This peer-reviewed study reports this substance is a significant skin sensitizer after oxidation. Johanna Bråred Christensson, Mihály Matura, Birgitta Gruvberger, Magnus Bruze & Ann-Therese Karlberg. 2010. Linalool--a significant contact sensitizer after air exposure. Contact dermatitis 62(1), 32-41.</p> <p>Component: LINALOOL This peer-reviewed study reports this substance is a significant skin sensitizer after oxidation. Johanna Bråred Christensson, Pia Forsström, Ann-Marie Wennberg, Ann-Therese Karlberg & Mihály Matura. 2009. Air oxidation increases skin irritation from fragrance terpenes. Contact dermatitis 60(1), 32-40.</p> <p>Component: LINALOOL This peer-reviewed study reports this substance is a significant skin sensitizer after oxidation. Deirdre A. Buckley. 2011. Allergy to oxidized linalool in the UK. Contact dermatitis 64(4), 240-1.</p> <p>Component: LINALOOL This peer-reviewed study reports this substance is a contact skin allergen. Mihály Matura, Ian R. White, Cecilia Svedman, Jeanne D. Johansen, An Goossens, Peter Frosch, Magnus Bruze, Klaus E. Andersen, Anna Börje, Maria Sköld & Ann-Therese Karlberg. 2005. Selected oxidized fragrance terpenes are common contact allergens. Contact dermatitis 52(6), 320-8.</p> <p>http://www.thegoodscentcompany.com/data/es1007471.html#tosaftey</p>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p>European information :</p> <p>Most important hazard(s):</p> <p><i>Xn - Harmful.</i></p> <p><i>R 36/38 - Irritating to skin and eyes.</i></p> <p><i>R 43 - May cause sensitisation by skin contact.</i></p> <p><i>S 24/25 - Avoid contact with skin and eyes.</i></p>
Lemon oil terpenes	Y		<p>https://echa.europa.eu/substance-information/-/substanceinfo/100.108.674</p> <p>Danger! According to the classification provided by companies to ECHA in CLP notifications this substance may be fatal if swallowed and enters airways, is very toxic to aquatic life with long lasting effects, is very toxic to aquatic life, is a flammable liquid and vapour, <i>causes skin irritation and may cause an allergic skin reaction.</i></p>
Levisticum Officinale Oil (Levisticum Officinale Leaf Oil)		Y	<p>https://chem.nlm.nih.gov/chemidplus/rn/startswith/8016-31-7</p> <p><i>Skin/eye irritant</i></p>
Linalool	Y		<p>https://chem.nlm.nih.gov/chemidplus/rn/startswith/78-70-6</p> <p><i>Skin/eye irritant</i></p> <p>https://www.ewg.org/guides/substances/3258-LINALOOL#.W312eOhKiUk</p> <p>Recognized by the European Union as a skin allergen. Allergen list - EU Cosmetics Directive</p> <p>The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p> <p>This peer-reviewed study reports this substance is a significant skin sensitizer after oxidation. Johanna Bråred Christensson, Mihály Matura, Birgitta Gruvberger, Magnus Bruze & Ann-Therese Karlberg. 2010. Linalool--a significant contact sensitizer after air exposure. Contact dermatitis 62(1), 32-41.</p> <p>This peer-reviewed study reports this substance is a significant skin sensitizer after oxidation. Johanna Bråred Christensson, Pia Forsström, Ann-Marie Wennberg, Ann-Therese Karlberg & Mihály Matura. 2009. Air oxidation increases skin irritation from fragrance terpenes. Contact dermatitis 60(1), 32-40.</p> <p>This peer-reviewed study reports this substance is a significant skin sensitizer after oxidation. Deirdre A. Buckley. 2011. Allergy to oxidized linalool in the UK. Contact dermatitis 64(4), 240-1.</p> <p>This peer-reviewed study reports this substance is a contact skin allergen. Mihály Matura, Ian R. White, Cecilia Svedman, Jeanne D. Johansen, An Goossens, Peter Frosch, Magnus Bruze, Klaus E. Andersen, Anna Börje, Maria Sköld & Ann-Therese Karlberg. 2005. Selected oxidized fragrance terpenes are common contact allergens. Contact dermatitis 52(6), 320-8.</p> <p>https://cosmeticsinfo.org/ingredient/linalool-0</p> <p>The Food and Drug Administration (FDA) includes Linalool on its list of substances considered Generally Recognized As Safe (GRAS) as flavoring substance. The safety of Linalool has been evaluated by the Research Institute for Fragrance Materials Expert Panel (REXPAN). Based on this evaluation, an International Fragrance Association (IFRA) Standard has been established. <i>The IFRA Standard restricts the use of Linalool in fragrances because of potential sensitization.</i></p> <p>More safety Information: Link to FDA Code of Federal Regulations for Linalool: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=182.60&SearchTerm=linalool</p>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			<p>The Joint FAO/WHO Expert Committee on Food Additives (JECFA) concluded that Linalool does not present a safety concern at current levels of intake when used as a flavoring agent.</p> <p>Link to the JECFA safety evaluation of Linalool: http://www.inchem.org/documents/jecfa/jecval/jec_1271.htm</p> <p>The Flavor and Extract Manufacturers Association Expert Panel has reviewed the safety of linalool and determined that it is Generally Recognized as Safe (GRAS) for use as a flavoring substance. <i>In Europe, Linalool is included on the list of "allergenic" substances.</i> The European Cosmetics Regulation requires manufacturers of cosmetics and personal care products to indicate the presence of certain "allergenic" substances in the list of ingredients if they are present above certain levels in the product (see Annex III). The presence of Linalool must be indicated in the list of ingredients when its concentration exceeds: 0.001% in leave-on the skin products 0.01% in products that are rinsed off the skin</p> <p>Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013</p> <p>http://www.thegoodscentscompany.com/data/rw1007872.html#tosafte</p> <p>European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 36/38 - Irritating to skin and eyes.</i> <i>R 43 - May cause sensitisation by skin contact.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i></p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i></p> <p>https://pubchem.ncbi.nlm.nih.gov/compound/6549#section=GHS-Classification Signal: Warning GHS Hazard Statements <i>H315 (96.96%): Causes skin irritation [Warning Skin corrosion/irritation]</i> <i>H317 (53.26%): May cause an allergic skin reaction [Warning Sensitization, Skin]</i></p> <p>Skin, Eye, and Respiratory Irritations <i>A skin irritant.</i> Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 2232 from HSDB</p> <p><i>... Linalool must be regarded as a skin irritant and should be seen as mildly irritant for man. ... Linalool is at most a moderate eye irritant; moreover, in about a third of human subjects it did not cause any eye irritation at 320 ppm.</i> Organization for Economic Cooperation and Development; Screening Information Data Set for LINALOOL (78-70-6) p.14 (March 2002). from HSDB</p> <p>NIOSH Toxicity Data https://pubchem.ncbi.nlm.nih.gov/compound/6549#section=NIOSH-Toxicity-Data&fullscreen=true</p>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower								
				Measurement	Date	System	Route/Organism	Dose	Effect	
				Skin and Eye Irritation	October 2017		eye /rabbit	100 µL	moderate	
				Skin and Eye Irritation	October 2017		eye /rabbit	0.1 mL/1H	moderate	
				Skin and Eye Irritation	October 2017		skin /guinea pig	100 mg/24H	moderate	
				Skin and Eye Irritation	October 2017		skin /human	32%/72H	mild	
				Skin and Eye Irritation	October 2017		skin /human	10%/2D		
				Skin and Eye Irritation	October 2017		skin /man	16 mg/48H	mild	
				Skin and Eye Irritation	October 2017		skin /rabbit	500 mg/24H	mild	
				Skin and Eye Irritation	October 2017		skin /rabbit	100 mg/24H	severe	
Linalyl Acetate	Y		<p>https://pubchem.ncbi.nlm.nih.gov/compound/8294#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements</p> <p><i>H315 (98.36%): Causes skin irritation [Warning Skin corrosion/irritation]</i></p> <p>Skin, Eye, and Respiratory Irritations <i>A severe skin irritant.</i> Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 2232 from HSDB</p> <p><i>Linalyl acetate (100%) appeared to be severely irritating to rabbit skin and moderately irritating to the skin of the guinea pig. In a test with miniature swines, application of 0.05 g linalyl acetate under a patch for 48 hours /caused/ no irritation</i> Organization for Economic Cooperation and Development; Screening Information Data Set for LINALYL ACETATE (115-95-7) p.11 (March 2002). Available from, as of July 14, 2008: http://www.chem.unep.ch/irptc/sids/OECDsids/sidspub.html from HSDB</p> <p>https://chem.nlm.nih.gov/chemidplus/rn/startswith/115-95-7 <i>Skin/eye irritant</i></p> <p>https://www.ewg.org/guides/substances/3259-LINALYLACETATE#.W31y2-hKiUk The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans.</p> <p>Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p>							

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p>http://www.thegoodscentscompany.com/data/rw1007892.html#tosaftey European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 36/38 - Irritating to skin and eyes.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i></p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i></p>
Mentha Arvensis Leaf Oil	Y		<p>http://www.thegoodscentscompany.com/data/es1003041.html#tosaftey European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 37/38 - Irritating to respiratory system and skin.</i></p> <p>https://www.ewg.org/guides/substances/6437-MENTHAARVENSISWILDMINTOIL#.W31vDuhKiUk Component: LINALOOL This peer-reviewed study reports this substance is a significant skin sensitizer after oxidation.</p> <p>Johanna Bråred Christensson, Mihály Matura, Birgitta Gruvberger, Magnus Bruze & Ann-Therese Karlberg. 2010. Linalool--a significant contact sensitizer after air exposure. Contact dermatitis 62(1), 32-41.</p> <p>Johanna Bråred Christensson, Pia Forsström, Ann-Marie Wennberg, Ann-Therese Karlberg & Mihály Matura. 2009. Air oxidation increases skin irritation from fragrance terpenes. Contact dermatitis 60(1), 32-40.</p> <p>Deirdre A. Buckley. 2011. Allergy to oxidized linalool in the UK. Contact dermatitis 64(4), 240-1.</p> <p>Component: LINALOOL This peer-reviewed study reports this substance is a contact skin allergen.</p> <p>Mihály Matura, Ian R. White, Cecilia Svedman, Jeanne D. Johansen, An Goossens, Peter Frosch, Magnus Bruze, Klaus E. Andersen, Anna Börje, Maria Sköld & Ann-Therese Karlberg. 2005. Selected oxidized fragrance terpenes are common contact allergens. Contact dermatitis 52(6), 320-8.</p> <p>The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans.</p> <p>Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p> <p>Component: LINALOOL Recognized by the European Union as a skin allergen Allergen list - EU Cosmetics Directive</p> <p>Component: LINALOOL The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p>
Menthyl Acetate	Y		<p>http://www.thegoodscentscompany.com/data/rw1046271.html#tosaftey European information : Most important hazard(s):</p>

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p><i>Xi - Irritant</i> <i>R 36/38 - Irritating to skin and eyes.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i></p>
Methyl Anthranilate	Y		<p>https://pubchem.ncbi.nlm.nih.gov/compound/8635#section=GHS-Classification Health Hazard SYMPTOMS: <i>This compound is an irritant to the skin. ACUTE/CHRONIC HAZARDS: This compound may cause irritation on contact.</i> (NTP, 1992). from CAMEO Chemicals</p> <p>Skin, Eye, and Respiratory Irritations Prolonged inhalation may lead to respiratory tract irritation. ...<i>Prolonged or repeated /skin or eye/ contact may result in mechanical irritation.</i> Becker Underwood, Inc; Material Safety Data Sheet for Methyl Anthranilate 134-20-3 (Date Revised: February 23, 2000). Available from, as of November 11, 2003: http://www.beckerunderwood.com/msds/rejexit_ff.html from HSDB</p> <p>https://chem.nlm.nih.gov/chemidplus/rn/startswith/134-20-3 Skin/eye irritant</p> <p>https://www.ewg.org/guides/substances/11032-METHYLANTHRANILATE#.W3yJwuhKiUk The European Commission's Scientific Committee on Consumer Safety reports this substance shows negative results for causing contact allergy in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p> <p>http://www.thegoodscentscompany.com/data/rw1008211.html#tosaftey European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 36/38 - Irritating to skin and eyes.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i></p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i></p>
Methyl Benzoate	Y	Y	<p>https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr578.pdf</p> <p>https://cosmeticsinfo.org/ingredient/methyl-benzoate The Food and Drug Administration (FDA) permits Methyl Benzoate, Ethyl Benzoate, Propyl Benzoate, Isopropyl Benzoate and Isobutyl Benzoate to be used as flavoring agents for direct addition to food. Butyl Benzoate is permitted for use as an indirect food additive as a component of adhesives.</p> <p>Link to FDA Code of Federal Regulations</p> <p>https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.515&SearchTerm=benzyl%20benzoate https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=175.105</p>

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p>The European Union lists salts and esters of benzoic acid (including Methyl Benzoate, Ethyl Benzoate, Propyl Benzoate, Butyl Benzoate, Isopropyl Benzoate and Isobutyl Benzoate) as preservatives that may be safely used in cosmetics at concentrations up to 0.5% (See Annex IV).</p> <p>Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013</p> <p>http://www.thegoodscentscompany.com/data/rw1015012.html#tosaftey</p> <p>European information : Most important hazard(s): Xn - Harmful. R 36/38 - Irritating to skin and eyes. R 42/43 - May cause sensitization by inhalation and skin contact. S 24/25 - Avoid contact with skin and eyes.</p>
Methyl Cinnamate	Y		<p>https://pubchem.ncbi.nlm.nih.gov/compound/637520#section=Safety-and-Hazards</p> <p>Signal: Warning GHS Hazard Statements</p> <p><i>H317 (100%): May cause an allergic skin reaction [Warning Sensitization, Skin]</i></p> <p>https://www.ewg.org/guides/substances/18329-METHYLCINNAMATE#.W3yEyuhKiUk</p> <p>The European Commission's Scientific Committee on Consumer Safety reports this substance shows some evidence of causing contact allergy in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p> <p>http://www.thegoodscentscompany.com/data/rw1417571.html#tosaftey</p> <p>European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 36/38 - Irritating to skin and eyes.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i></p>
Methyl Salicylate	Y		<p>https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr302.pdf https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/TR766.pdf</p> <p>https://chem.nlm.nih.gov/chemidplus/rn/startswith/119-36-8 <i>Skin/eye irritant</i></p> <p>https://pubchem.ncbi.nlm.nih.gov/compound/4133#section=Safety-and-Hazards</p> <p>Signal: Warning GHS Hazard Statements <i>H315 (23.08%): Causes skin irritation [Warning Skin corrosion/irritation]</i></p> <p>Health Hazard <i>Harmful if swallowed, inhaled, absorbed through skin.</i> Vapor mist is irritating to the eyes, mucous membranes, upper respiratory tract and skin. Ingestion of relatively small amount causes severe poisoning and death. Causes nausea, vomiting, acidosis, pulmonary edema, pneumonia, convulsions and death. (USCG, 1999) from CAMEO Chemicals</p> <p>Effects of Short Term Exposure <i>The substance is irritating to the eyes and skin.</i> The substance may cause effects on the central nervous system. This may result in shock and death. The effects may be delayed. Medical observation is indicated.</p>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p>from ILO-ICSC</p> <p>http://www.thegoodscentscompany.com/data/rw1008472.html#tosafy</p> <p>European information : Most important hazard(s): Xn - Harmful. <i>R 36/38 - Irritating to skin and eyes.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i></p> <p>https://www.ewg.org/guides/substances/3576-METHYLSALICYLATE#.W3yBzuhKiUk</p> <p>The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p> <p>https://cosmeticsinfo.org/ingredient/methyl-salicylate</p> <p>The Food and Drug Administration (FDA) has reviewed the safety of Salicylic Acid and Methyl Salicylate and permits their use as indirect food additives. Salicylic Acid is approved for use in Over-the-Counter (OTC) drug products. Salicylic acid is widely used as an FDA approved safe and effective acne drug product. It is also approved for use in OTC drugs for corn, callus and wart removal, as well as in antidandruff OTC drug products. Ethylhexyl Salicylate and TEA-Salicylate are permitted by FDA for use as active ingredients in OTC sunscreen drug products. Ethylhexyl Salicylate may be used at concentrations up to 5%, and TEA-Salicylate may be used at concentrations up to 12%.</p> <p>Link to the FDA Code of Federal Regulations for Salicylic Acid, Sodium Salicylate, Methyl Salicylate, and Octyl (Ethylhexyl) Salicylate</p> <p>Acne Active Ingredients Adhesives Sunscreen Active Ingredients Wart Remover Active Ingredients Corn and Callus Remover Active ingredients Control of Dandruff</p> <p>Salicylic Acid it salts are listed in the Cosmetics Directive of the European Union and may be used as preservatives in cosmetics and personal care products at a maximum concentration of 0.5% (see Annex VI). In Europe, for uses other than as a preservative, Salicylic Acid may be used in rinse-off hair products at concentrations up to 3%, and in other products at concentrations up to 2% (see Annex III). Salicylic Acid should not to be used in products for children under 3 years of age, except for shampoo formulations. Ethylhexyl Salicylate is listed in the Cosmetics Directive of the European Union and may be used as a UV filter at a concentration up to 5% (see Annex VII).</p> <p>Health Canada permits the use of Salicylic Acid in cosmetics and personal care products in concentrations equal to or less than 2%.</p> <p>Ethylhexyl Salicylate (up to 6%) and TEA-Salicylate (up to 12%) are permitted for use in sunscreen products in Canada.</p>
Myristica Fragrans (Nutmeg) Kernel Oil (Nutmeg oil)	Y	Y	<p>https://pubchem.ncbi.nlm.nih.gov/compound/6850746#section=Canonical-SMILES</p> <p>https://chem.nlm.nih.gov/chemidplus/rn/startswith/8008-45-5 Skin/eye irritant</p> <p>https://www.ewg.org/guides/substances/3802-MYRISTICAFRAGRANSNUTMEGKERNELOIL#.W3x8BuhKiUk</p> <p>Component: D-LIMONENE Recognized by the European Union as a skin allergen. Allergen list - EU Cosmetics Directive</p> <p>Impurity: FORMALDEHYDE</p>

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
Myroxylon Balsamum (Balsam Tolu) Resin	Y		<p>Causes skin irritation. NIOSH Pocket Guide to Chemical Hazards – Centers for Disease Control and Prevention (CDC)</p> <p>https://chem.nlm.nih.gov/chemidplus/rn/startswith/9000-64-0 <i>Skin/eye irritant</i></p> <p>http://www.thegoodscentscompany.com/data/rs1011391.html European information : Most important hazard(s): Xi - Irritant <i>R 43 - May cause sensitisation by skin contact.</i></p>
Myroxylon Pereirae (Balsam Peru) Oil	Y		<p>https://www.ewg.org/skindeep/ingredient/720874/MYROXYLON_PEREIRAE_(BALSAM_PERU)_OIL/#.W3x4b-hKiUk</p> <p>http://www.thegoodscentscompany.com/data/es1009811.html#tosaftey European information : Most important hazard(s): Xi - Irritant <i>R 38 - Irritating to skin.</i> <i>R 43 - May cause sensitisation by skin contact.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i> <i>S 28 - After contact with skin, wash immediately with plenty of water.</i></p>
Nonan-1-ol (Nonyl Alcohol)	Y		<p>https://pubchem.ncbi.nlm.nih.gov/compound/8914#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements <i>H315 (17.45%): Causes skin irritation [Warning Skin corrosion/irritation]</i></p>
Octan-2-one (2-Octanone)		Y	<p>https://pubchem.ncbi.nlm.nih.gov/compound/8093#section=Hazards-Identification Skin, Eye, and Respiratory Irritations 2-Octanone has a relatively low toxicity. <i>Direct skin contact may cause defatting and irritation of the skin.</i> Bingham, E.; Cohrssen, B.; Powell, C.H.; Patty's Toxicology Volumes 1-9 5th ed. John Wiley & Sons. New York, N.Y. (2001)., p. 6:301. from HSDB</p> <p>http://www.thegoodscentscompany.com/data/rw1001751.html#tosaftey European information : Most important hazard(s): Xn - Harmful. <i>R 21 - Harmful in contact with skin.</i> <i>R 36/37/38 - Irritating to eyes, respiratory system, and skin.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i></p>
Opoponax (sweet myrrh)	Y		<p>https://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_025b.pdf According to the results of these tests, summarized in the table, five of the tested samples (2 extracts and 3 oils) gave some positive results indicating that Opoponax products may have a <i>mild sensitizing potential depending on the origin and the quality of the product.</i> In the introductory report (ref. 29) it is stated that the earlier studies with positive results were most likely due to the utilization of samples that contained undefined impurities. The more recent studies yielding negative results used better-defined materials. However, in the same report it is also stated that the source of the samples with positive results is unknown, and may have been obtained from <i>Pastinaca opopanax</i> L. (Fam: Umbelliferare) instead of from genuine opoponax gums from <i>Commiphora erythraea</i> var. <i>glabrescens</i> Engler (Fam: Burseraceae). Taking also into consideration that the most recent studies mentioned above were carried out in 1979-1980, these two partially contradicting statements cannot be evaluated.</p>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
p-Cresol	Y		<p>https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr277.pdf</p> <p>https://cosmeticsinfo.org/ingredient/p-cresol</p> <p>The Food and Drug Administration (FDA) permits the use of Thymol as a direct and food additive (as a flavoring substance) and as an indirect food additive (for use in paper an paperboard in contact with food).</p> <p>Link to FDA Code of Federal Regulations for Thymol</p> <p>https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.515&SearchTerm=thymol https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=176.180&SearchTerm=thymol</p> <p>In the European Union, p-Chloro-m-Cresol, Sodium p-Chloro-m-Cresol at concentrations up to 0.2% and o-Cymen-5-ol (4-Isopropyl-m-cresol) at concentrations up to 0.1% are allowed to be used as preservatives (see Annex VI).</p> <p>Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013</p> <p>https://chem.nlm.nih.gov/chemidplus/rn/106-44-5 <i>Skin/eye irritant</i> Tumor Data</p> <p>http://www.thegoodscentscompany.com/data/rw1003851.html#tosafte European information : Most important hazard(s): T - Toxic. R 24/25 - <i>Toxic in contact with skin and if swallowed.</i> R 34 - Causes burns. R 36/37/38 - <i>Irritating to eyes, respiratory system, and skin.</i> S 24/25 - <i>Avoid contact with skin and eyes.</i></p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Acute toxicity, Dermal (Category 3), H311</i> <i>Skin corrosion (Category 1B), H314</i></p> <p>https://pubchem.ncbi.nlm.nih.gov/compound/2879#section=Hazards-Identification Signal: Danger GHS Hazard Statements H311: <i>Toxic in contact with skin [Danger Acute toxicity, dermal]</i> H314: <i>Causes severe skin burns and eye damage [Danger Skin corrosion/irritation]</i> H351: <i>Suspected of causing cancer [Warning Carcinogenicity]</i></p> <p>Health Hazard <i>SKIN: Intense burning, loss of feeling, white discoloration and softening. Gangrene may occur. (USCG, 1999)</i> from CAMEO Chemicals</p> <p>Skin, Eye, and Respiratory Irritations</p>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower									
Chemical	Baby Powder	Shower-to-Shower							
			<p>... Causes severe eye and skin burns. ... Irritating to skin, eyes, and respiratory system. Symptoms include severe irritation of eyes with tearing, conjunctivitis, and corneal edema. <i>May act as a skin sensitizer.</i> National Fire Protection Association; Fire Protection Guide to Hazardous Materials. 14TH Edition, Quincy, MA 2010, p. 49-48 from HSDB</p> <p>NIOSH Toxicity Data</p> <table> <tr> <td>Tumorigenic Data</td><td>June 2017</td><td>skin/mouse</td><td>lowest published toxic dose: 2280 mg/kg/20W-intermittent</td><td> <p>Tumorigenic: Neoplastic by RTECS criteria</p> <p>Skin and Appendages: Tumors</p> </td></tr> </table>		Tumorigenic Data	June 2017	skin/mouse	lowest published toxic dose: 2280 mg/kg/20W-intermittent	<p>Tumorigenic: Neoplastic by RTECS criteria</p> <p>Skin and Appendages: Tumors</p>
Tumorigenic Data	June 2017	skin/mouse	lowest published toxic dose: 2280 mg/kg/20W-intermittent	<p>Tumorigenic: Neoplastic by RTECS criteria</p> <p>Skin and Appendages: Tumors</p>					
p-Cymene	Y		<p>https://pubchem.ncbi.nlm.nih.gov/compound/7463#section=Hazards-Identification <i>p-Cymene is reported to be a primary skin irritant ...</i> Monograph on Fragrance Raw Materials: p-Cymene; Food and Cosmetics Toxicology 12 (3): 401-2 (1974) from HSDB</p> <p>http://www.thegoodscentscompany.com/data/rw1032712.html#tosaftey European information : Most important hazard(s): Xn - Harmful. <i>R 36/37/38 - Irritating to eyes, respiratory system, and skin..</i> <i>S 24/25 - Avoid contact with skin and eyes..</i></p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i></p>						
Pelargonium Graveolens Flower Oil (Geranium)	Y		<p>https://www.ewg.org/guides/substances/4320-PELARGONIUMGRAVEOLENSGERANIUMEXTRACT#.W3xhiehKiUk The European Commission's Scientific Committee on Consumer Safety reports this substance is an established <i>contact allergen</i> in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p> <p>Directive Component: GERANIOL Recognized by the European Union as a skin allergen. Allergen list - EU Cosmetics Directive Component: GERANIOL The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p> <p>Component: LINALOOL Recognized by the European Union as a skin allergen. Allergen list - EU Cosmetics Directive.</p> <p>Component: LINALOOL The European Commission's Scientific Committee on Consumer Safety reports this substance is an established contact allergen in humans. Opinion on Fragrance allergens in cosmetics (2011) - EU Cosmetics Directive</p> <p>Component: LINALOOL This peer-reviewed study reports this substance is a significant skin sensitizer after oxidation. Johanna Bråred Christensson, Mihály Matura, Birgitta Gruvberger, Magnus Bruze & Ann-Therese Karlberg. 2010. Linalool--a significant contact sensitizer after air exposure. Contact dermatitis 62(1), 32-41.</p>						

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p>Component: LINALOOL This peer-reviewed study reports this substance is a significant skin sensitizer after oxidation. Deirdre A. Buckley. 2011. Allergy to oxidized linalool in the UK. Contact dermatitis 64(4), 240-1.</p> <p>Component: LINALOOL This peer-reviewed study reports this substance is a contact skin allergen. Mihály Matura, Ian R. White, Cecilia Svedman, Jeanne D. Johansen, An Goossens, Peter Frosch, Magnus Bruze, Klaus E. Andersen, Anna Börje, Maria Sköld & Ann-Therese Karlberg. 2005. Selected oxidized fragrance terpenes are common contact allergens. Contact dermatitis 52(6), 320-8.</p> <p>https://pubchem.ncbi.nlm.nih.gov/compound/637566#section=GHS-Classification (Geraniol): Signal: Danger GHS Hazard Statements</p> <p><i>H315 (98.89%): Causes skin irritation [Warning Skin corrosion/irritation]</i> <i>H317 (99.59%): May cause an allergic skin reaction [Warning Sensitization, Skin]</i></p> <p>Skin, Eye, and Respiratory Irritations <i>A severe human skin irritant.</i> Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 1440. from HSDB</p>
Pentadecalactone <i>(omega-pentadecalactone)</i> <i>(Oxacyclohexadecan-2-one)</i>	Y		<p>https://pubchem.ncbi.nlm.nih.gov/compound/235414#section=GHS-Classification Signal: Warning GHS Hazard Statements</p> <p><i>H317 (18.4%): May cause an allergic skin reaction [Warning Sensitization, Skin]</i></p> <p>http://www.thegoodscentscompany.com/data/rw1004211.html#tosaftey European information : Most important hazard(s): <i>S 24/25 - Avoid contact with skin and eyes.</i></p>
Petitgrain oil, Paraguay <i>(Citrus aurantium fruit oil)</i>	Y		<p>https://echa.europa.eu/substance-information/-/substanceinfo/100.252.174 Essential oil of Petitgrain obtained from the leaves and twigs of Citrus aurantium (Rutaceae) by distillation Danger! According to the classification provided by companies to ECHA in REACH registrations this substance may be fatal if swallowed and enters airways, is toxic to aquatic life with long lasting effects, causes serious eye irritation and <i>causes skin irritation.</i></p>
Phenethyl Acetate	Y		<p>https://pubchem.ncbi.nlm.nih.gov/compound/7654#section=Hazards-Identification Signal: Danger GHS Hazard Statements</p> <p>http://www.thegoodscentscompany.com/data/rw1010032.html#tosaftey European information : Most important hazard(s): <i>S 24/25 - Avoid contact with skin and eyes.</i></p>
Phenethyl Alcohol	Y	Y	<p>https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr134.pdf https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/prn547.PDF</p>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower							
Chemical	Baby Powder	Shower-to-Shower					
			<p>http://www.thegoodscentscompany.com/data/rw1010052.html#tosaftey European information : Most important hazard(s): Xn - Harmful. <i>R 21/22 - Harmful in contact with skin and if swallowed.</i> <i>R 36/38 - Irritating to skin and eyes.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i></p> <p>https://cosmeticsinfo.org/ingredient/phenethyl-alcohol-0 More safety Information:</p> <p>Link to FDA Code of Federal Regulations for Phenethyl Alcohol https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=172.515&SearchTerm=phenethyl%20alcohol</p> <p>Phenethyl Alcohol may be used in cosmetics and personal care products marketed in Europe according to the general provisions of the Cosmetics Regulation of the European Union.</p> <p>Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013</p> <p>https://www.ewg.org/guides/substances/4400-PHENETHYLALCOHOL#.W3xBDehKiUk The European Commission's Scientific Committee on Consumer Safety reports this substance shows some evidence of causing <i>contact allergy in humans</i>. Opinion on Fragrance allergens in cosmetics (2011) – EU Cosmetics Directive</p> <p>https://pubchem.ncbi.nlm.nih.gov/compound/6054#section=GHS-Classification Signal: Warning</p> <p>Effects of Short Term Exposure <i>The substance is irritating to the eyes, skin and respiratory tract.</i> The substance may cause effects on the central nervous system. If swallowed the substance may cause vomiting and could result in aspiration pneumonitis. from ILO-ICSC*</p> <p>Effects of Long Term Exposure Animal tests show that this substance possibly causes toxicity to human reproduction or development. from ILO-ICSC*</p> <p>Skin Symptoms Redness. from ILO-ICSC*</p> <p><i>* The International Chemical Safety Cards (ICSC) are data sheets intended to provide essential safety and health information on chemicals in a clear and concise way. The primary aim of the cards is to promote the safe use of chemicals in the workplace.</i></p> <p>https://pubchem.ncbi.nlm.nih.gov/compound/6054#section=Toxicity From NIOSH</p>				
			Skin and Eye Irritation	eye /rabbit	12 gm/10M	mild	July 2016

Ingredient List – Johnson's Baby Powder & Shower-to-Shower								
Chemical	Baby Powder	Shower-to-Shower						
			Skin and Eye Irritation		eye /rabbit	750 µg/24H	severe	July 2016
			Skin and Eye Irritation		skin /guinea pig	100%	mild	July 2016
			Skin and Eye Irritation		skin /guinea pig	100 mg/24H	moderate	July 2016
			Skin and Eye Irritation		skin /rabbit	100 mg/24H	moderate	July 2016
Phenethyl Benzoate	Y		http://www.thegoodscentscompany.com/data/rw1012671.html#tosaftey European information : Most important hazard(s): Xi - Irritant <i>R 36/38 - Irritating to skin and eyes.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i>					
Phenoxyethanol	Y		https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr139.pdf https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PR609.pdf https://cosmeticsinfo.org/ingredient/phenoxyethanol-0 European Union (E.U.) Regulation (EC) No. 1223/2009 of the European Union lists phenoxyethanol in Annex V, the list of preservatives allowed in cosmetic products. The maximum concentration in ready for use concentrations is 1.0%. https://chem.nlm.nih.gov/chemidplus/rn/122-99-6 <i>Skin/eye irritant</i> https://pubchem.ncbi.nlm.nih.gov/compound/31236#section=GHS-Classification Signal: Warning GHS Hazard Statements <i>H315 (75.94%): Causes skin irritation [Warning Skin corrosion/irritation]</i> A skin and severe eye irritant. Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 2904 from HSDB					
phenylacetaldehyde	Y		https://www.ewg.org/guides/substances/16215-PHENYLACETALDEHYDE#.W3w8T-hKiUk The European Commission's Scientific Committee on Consumer Safety reports this substance shows some evidence of causing contact allergy in humans Opinion on Fragrance allergens in cosmetics (2011) EU Cosmetics Directive https://pubchem.ncbi.nlm.nih.gov/compound/998#section=GHS-Classification Signal: Danger					

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower																			
Chemical	Baby Powder	Shower-to-Shower																	
			<div>GHS Hazard Statements</div> <div>H314 (74.67%): Causes severe skin burns and eye damage [Danger Skin corrosion/irritation]</div> <div>H317 (96.46%): May cause an allergic skin reaction [Warning Sensitization, Skin]</div> <div>http://www.thegoodscentscompany.com/data/rw1009931.html#tosafy</div> <div>European information :</div> <div>Most important hazard(s):</div> <div>Xn - Harmful</div> <div>R 36/37/38 - Irritating to eyes, respiratory system, and skin.</div> <div>R 43 - May cause sensitisation by skin contact.</div> <div>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)</div> <div>Skin irritation (Category 2), H315</div>																
p-Methyl Acetophenone	Y		<div>https://chem.nlm.nih.gov/chemidplus/rn/122-00-9</div> <div>Skin/eye irritant</div> <div>https://pubchem.ncbi.nlm.nih.gov/compound/8500#section=GHS-Classification</div> <div>Signal: Warning</div> <div>GHS Hazard Statements</div> <div>H315 (79.94%): Causes skin irritation [Warning Skin corrosion/irritation]</div> <div>http://www.thegoodscentscompany.com/data/rw1008191.html#tosafy</div> <div>European information :</div> <div>Most important hazard(s):</div> <div>Xn - Harmful.</div> <div>R 22 - Harmful if swallowd.</div> <div>R 36/38 - Irritating to skin and eyes.</div> <div>S 24/25 - Avoid contact with skin and eyes.</div>																
Pogostemon Cablin Oil (Patchouli)	Y	Y	<div>https://chem.nlm.nih.gov/chemidplus/rn/8014-09-3</div> <div>Skin/eye irritant</div> <div>http://www.thegoodscentscompany.com/data/es1031631.html#tosafy</div> <div>European information :</div> <div>Most important hazard(s):</div> <div>Xi - Irritant</div> <div>R 36/38 - Irritating to skin and eyes.</div> <div>S 24/25 - Avoid contact with skin and eyes.</div> <div>Signal word Warning</div> <div>Hazard statement(s)</div> <div>H316 - Causes mild skin irritation</div>																
Propanedioic acid, diethyl ester (Diethyl Malonate)	Y		<div>https://pubchem.ncbi.nlm.nih.gov/compound/7761#section=Toxicity</div> <table><tr><td>Measurement</td><td>System</td><td>Route/Organism</td><td>Dose</td><td>Effect</td><td>Date</td></tr><tr><td>Skin and Eye Irritation</td><td></td><td>skin /rabbit</td><td>500 mg/24H</td><td>mild</td><td>January 1997</td></tr></table>					Measurement	System	Route/Organism	Dose	Effect	Date	Skin and Eye Irritation		skin /rabbit	500 mg/24H	mild	January 1997
Measurement	System	Route/Organism	Dose	Effect	Date														
Skin and Eye Irritation		skin /rabbit	500 mg/24H	mild	January 1997														

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower																	
Chemical	Baby Powder	Shower-to-Shower															
Propanoic acid, phenylmethyl ester (Benzyl Propionate)	Y	Y	http://www.thegoodscentscompany.com/data/rw1001772.html#tosafte European information : Most important hazard(s): S 24/25 - Avoid contact with skin and eyes. Signal word Warning														
Propylene Glycol		Y	https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PR560.PDF https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr77.pdf https://cosmeticsinfo.org/ingredient/propylene-glycol Safety Information: United States FDA: The agency includes propylene glycol on its list of substances considered Generally Recognized As Safe (GRAS) for direct addition to food. Polypropylene glycol is also permitted as an indirect food additive for use as a de-foaming agent. NTP: In 2003, the National Toxicology Program's (NTP) Center for the Evaluation of Risk to Human Reproduction (CERHR) Expert Panel reviewed the reproductive and developmental effects potential of propylene glycol and concluded that there is "negligible concern for reproductive or developmental toxicity to humans." European Union (EU) Propylene glycol and PPGs may be used in cosmetics and personal care products marketed in Europe according to the general provisions of the Cosmetics Regulation of the European Union. https://www.ewg.org/guides/substances/4889-PROPYLENEGLYCOL#.W3wnlehKiUk The OECD concluded that <i>Propylene Glycol does not cause sensitization by skin contact</i> . Organisation for Economic Co-Operation and Development. 2001. Propylene glycol CAS No. 57-55-6. SIDS Initial Assessment Report for 11th SIAM. The OECD concluded that <i>Propylene Glycol is not a skin irritant</i> . Organisation for Economic Co-Operation and Development. 2001. Propylene glycol CAS No. 57-55-6. SIDS Initial Assessment Report for 11th SIAM. The Agency for Toxic Substances and Disease Registry concluded that <i>Propylene Glycol has marginal irritant properties</i> . U.S. Department of Health and Human Services - Agency for Toxic Substances and Disease Registry. 1997. Toxicological Profile For Propylene Glycol. The Agency for Toxic Substances and Disease Registry found cases of sensitivity recorded in the <i>Propylene Glycol literature and concluded that it might be a sensitizer</i> . U.S. Department of Health and Human Services - Agency for Toxic Substances and Disease Registry. 1997. Toxicological Profile For Propylene Glycol. https://pubchem.ncbi.nlm.nih.gov/compound/1030#section=NIOHS-Toxicity-Data&fullscreen=true <table><tr><td>Skin and Eye Irritation</td><td>June 2017</td><td></td><td>eye /rabbit</td><td>100 mg</td><td>mild</td></tr><tr><td>Skin and Eye Irritation</td><td>June 2017</td><td></td><td>eye /rabbit</td><td>500 mg/24H</td><td>mild</td></tr></table>			Skin and Eye Irritation	June 2017		eye /rabbit	100 mg	mild	Skin and Eye Irritation	June 2017		eye /rabbit	500 mg/24H	mild
Skin and Eye Irritation	June 2017		eye /rabbit	100 mg	mild												
Skin and Eye Irritation	June 2017		eye /rabbit	500 mg/24H	mild												

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower								
Chemical	Baby Powder	Shower-to-Shower						
			Skin and Eye Irritation	June 2017		skin /child	30%/96H-continuous	moderate
			Skin and Eye Irritation	June 2017		skin /human	500 mg/7D	mild
			Skin and Eye Irritation	June 2017		skin /human	104 mg/3D- intermittent	moderate
			Skin and Eye Irritation	June 2017		skin /human	20%	
			Skin and Eye Irritation	June 2017		skin /man	10%/2D	
			Skin and Eye Irritation	June 2017		skin /woman	30%/96H open irritation test	mild
			Mutation Data	June 2017	Cytogenetic Analysis	subcutaneous/mouse	8000 mg/kg	
			Mutation Data	June 2017	Cytogenetic Analysis	fibroblast/hamster	32 gm/L	
Santalum Album (Sandalwood) Oil	Y		http://www.thegoodscentscompany.com/data/es1010871.html#tosafv European information : Most important hazard(s): <i>Xi - Irritant</i> R 36/38 - Irritating to skin and eyes. R 43 - May cause sensitisation by skin contact. S 24/25 - Avoid contact with skin and eyes. GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Skin irritation (Category 2), H315</i> <i>Skin sensitisation (Category 1), H317</i> https://www.ewg.org/guides/substances/5309-SANTALUMALBUMSANDALWOODOIL#.W3wkbehKiUk Some concern for skin allergies & irritation					
Tartaric Acid (<i>laevo-(+)-tartaric acid</i>)	Y		http://www.thegoodscentscompany.com/data/rw1034811.html European information : Most important hazard(s): <i>Xi - Irritant</i> R 36/37/38 - Irritating to eyes, respiratory system, and skin. S 24/25 - Avoid contact with skin and eyes. https://cosmeticsinfo.org/ingredient/tartaric-acid Safety Information: The Food and Drug Administration (FDA) has reviewed the safety of Potassium Sodium Tartrate and has affirmed its status as Generally Recognized as Safe (GRAS) as a direct food substance. FDA has approved the use of Tartaric Acid and Potassium Sodium Tartrate in Over-the-Counter (OTC) antacid drug products.					

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
			<p>More safety Information: Tartaric acid is metabolically inert in the human body. Link to FDA Code of Federal Regulations for Tartaric Acid</p> <p>https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=184.1099&SearchTerm=tartaric%20acid https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=331.11&SearchTerm=tartaric%20acid</p> <p>Link to FDA Code of Federal Regulations for Potassium Sodium Tartrate</p> <p>https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=184.1804&SearchTerm=sodium%20potassium%20tartrate https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=331.11&SearchTerm=sodium%20potassium%20tartrate</p> <p>Tartaric Acid and its salts may be used in cosmetics and personal care products marketed in the Europe according to the https://cosmeticsinfo.org/glossary/letter_g#General_Provisions_of_the_Cosmetics_Regulation_of_the_European_Union</p> <p>Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013</p>
TBHQ (t-Butylhydroquinone)		Y	<p>https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr118.pdf https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PR609.pdf</p> <p>https://pubchem.ncbi.nlm.nih.gov/compound/16043#section=GHS-Classification</p> <p>Signal: Warning GHS Hazard Statements</p> <p><i>H312 (27.89%): Harmful in contact with skin [Warning Acute toxicity, dermal]</i> <i>H315 (20.64%): Causes skin irritation [Warning Skin corrosion/irritation]</i> <i>H317 (32.21%): May cause an allergic skin reaction [Warning Sensitization, Skin]</i></p> <p>Health Hazard SYMPTOMS: Symptoms of exposure to this compound include irritation of the skin and eyes and dermatitis. (NTP, 1992)</p> <p>https://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+838</p> <p>Clinical Effects: 0.2.1 SUMMARY OF EXPOSURE 0.2.1.1 ACUTE EXPOSURE ... D) WITH THERAPEUTIC USE 1) DERMAL: Localized contact dermatitis, pruritus, dry skin, burning, desquamation, erythema, brown or orange-brown nail discoloration, paradoxical ochronosis-like hyperpigmentation of the skin, and hypersensitivity reactions.</p>
Terpineol	Y	Y	<p>https://pubchem.ncbi.nlm.nih.gov/compound/17100#section=GHS-Classification</p> <p>Signal: Warning GHS Hazard Statements</p> <p><i>H315 (100%): Causes skin irritation [Warning Skin corrosion/irritation]</i></p>

Ingredient List – Johnson's Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p>HUMAN EXPOSURE AND TOXICITY: In human subjects, alpha-terpineol had a low irritative potency but a strong odor. <i>Two dermatitis patients were reported to be sensitized to alpha-terpineol, although attempts to induce skin sensitization in volunteers using a dilute solution of alpha-terpineol were unsuccessful.</i> ANIMAL STUDIES: <i>In rabbits neat alpha-terpineol was a moderate skin irritant.</i></p> <p>http://www.thegoodscentscompany.com/data/rw1011252.html#tosafy</p> <p>European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 36/38 - Irritating to skin and eyes.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i></p> <p>Hazards identification</p> <p><i>Skin irritation (Category 2), H315</i></p>
Trichloromethyl Phenyl Carbonyl Acetate (Rosacetol)		Y	<p>http://www.thegoodscentscompany.com/data/rw1002671.html#tosafy</p> <p>European information : Most important hazard(s): <i>Xi - Irritant</i> <i>R 36/38 - Irritating to skin and eyes.</i> <i>S 24/25 - Avoid contact with skin and eyes.</i></p>
Undecylenal <i>Undec-10-enal</i> <i>10-undecenal (aldehyde C-11 undecylenic)</i>	Y		<p>https://www.ewg.org/guides/substances/15138-UNDECYLENAL#.W3sGQehKiUk</p> <p>This substance is Generally Recognized as Safe (GRAS) as a food additive by the US Food and Drug Administration <i>Only in: Household Cleaners</i> low Concer FDA - Priority based Assessment of Food Additive (PAFA) - U.S. Food and Drug Administration (FDA)</p> <p>http://www.thegoodscentscompany.com/data/rw1000332.html#tosafy</p> <p>Most important hazard(s): <i>N - Dangerous for the environment.</i> <i>R 36/38 - Irritating to skin and eyes.</i> <i>R 43 - May cause sensitisation by skin contact.</i></p> <p>GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) <i>Acute toxicity, dermal (Category 5), H313</i> <i>Skin irritation (Category 2), H315</i> <i>Skin sensitisation (Category 1), H317</i></p> <p>Signal word Warning Hazard statement(s) <i>H313 - May be harmful in contact with skin</i> <i>H315 - Causes skin irritation</i> <i>H317 - May cause an allergic skin reaction</i></p> <p>https://pubchem.ncbi.nlm.nih.gov/compound/8187#section=GHS-Classification</p> <p>Signal: Warning GHS Hazard Statements <i>H315 (99.9%): Causes skin irritation [Warning Skin corrosion/irritation]</i> <i>H317 (91%): May cause an allergic skin reaction [Warning Sensitization, Skin]</i></p>

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
			<p>EPA Safer Chemical</p> <p>10-Undecenal - Yellow triangle - The chemical has met Safer Choice Criteria for its functional ingredient-class, but has some hazard profile issues. Specifically, a chemical with this code is not associated with a low level of hazard concern for all human health and environmental endpoints. (See Safer Choice Criteria). While it is a best-in-class chemical and among the safest available for a particular function, the function fulfilled by the chemical should be considered an area for safer chemistry innovation.</p>
Vanillin	Y		<p>http://www.thegoodscentscompany.com/data/rw1011712.html#tosafte https://chem.nlm.nih.gov/chemidplus/name/vanillin</p>
Vetiveria Zizanoides Root Oil	Y		<p>https://www.ewg.org/skindeep/ingredient/724810/VETIVERIA_ZIZANOIDES_ROOT_OIL/#.W3sAhuhKiUk</p> <p>Multiple, additive exposure sources</p> <p><i>Irritation (skin, eyes, or lungs)</i></p> <p>One or more animal studies show skin irritation at low doses RTECS®- Food and Cosmetics Toxicology</p> <p>Organ system toxicity (non-reproductive)</p> <p>Classified as not expected to be potentially toxic or harmful Environment Canada Domestic Substance List</p> <p>http://www.thegoodscentscompany.com/data/es1695591.html#tosafte</p> <p>Most important hazard(s):</p> <p>Xi - Irritant</p> <p>R 38 - Irritating to skin.</p>

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
1-Phenylethyl acetate (Methylphenylcarbiny acetate)	Y		http://www.thegoodscentscompany.com/data/rw1011092.html European information : Most important hazard(s): S 24/25 - Avoid contact with skin and eyes. Signal word Warning
3,7-Dimethylnona-2,6-dienentrile (3,7-Dimethylnona-2,6-dienentrile Homogeranyl nitrile Lemonile (Givaudan))		Y	http://www.thegoodscentscompany.com/data/rw1042831.html#tosafte European information : Most important hazard(s): S 24/25 - Avoid contact with skin and eyes.
3, 7-Dimethylocta-2,6-dien-1-yl phenylacetate (geranyl phenyl acetate)	Y		Trans-3,7-Dimethyl-2,6-octadien-1-yl phenylacetate or Geranyl phenylacetate ???
4-(2,5,6,6-Tetramethylcyclohex-2-en-1-yl)but-3-en-2-one (4-(2,5,6,6-Tetramethyl-2-cyclo-hexen-1-yl)-3-buten-2-one Methyl-alpha-ionone)	Y		http://www.thegoodscentscompany.com/data/rw1006691.html#tosafte European information : Most important hazard(s): None - None found. S 24 - Avoid contact with skin.
Acetic acid, anhydride, reaction products with 1,5,10-trimethyl-1,5,9-cyclododecatene		Y	https://pubchem.ncbi.nlm.nih.gov/compound/53422908#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements H317 (97.13%): May cause an allergic skin reaction [Warning Sensitization, Skin] https://echa.europa.eu/substance-information/-/substanceinfo/100.105.384 Warning! According to the classification provided by companies to ECHA in REACH registrations this substance is very toxic to aquatic life, is very toxic to aquatic life with long lasting effects and may cause an allergic skin reaction.
Aloe Barbadensis Leaf Extract		Y	https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr274.pdf http://www.ema.europa.eu/docs/en_GB/document_library/Herbal_-_HMPC_assessment_report/2017/04/WC500225527.pdf
Amyris Balsamifera Bark Oil		Y	No Data

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
(West Indian sandalwood oil)			
Anthemis Nobilis Flower		Y	<p>https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PR653.pdf (Anthemis Nobilis Flower Extract, oil, water)</p> <p>Int J Toxicol. 2017 May/Jun;36(1_suppl):57S-66S. doi: 10.1177/1091581817705620. Safety Assessment of Anthemis nobilis-Derived Ingredients as Used in Cosmetics. Johnson W Jr, Heldreth B, Bergfeld WF, Belsito DV, Hill RA, Klaassen CD, Liebler DC, Marks JG Jr, Shank RC, Slaga TJ, Snyder PW, Andersen FA. Abstract Anthemis nobilis (Roman chamomile) flower extract, anthemis nobilis flower oil, anthemis nobilis flower powder, and anthemis nobilis flower water are ingredients that function as fragrance ingredients and skin-conditioning agents in cosmetic products. These ingredients are being used at concentrations up to 10% (anthemis nobilis flower water) in cosmetic products. The available data indicate that these 4 ingredients are not irritating or sensitizing. Chemical composition data and the low use concentrations suggest that systemic toxicity would not be likely if percutaneous absorption of constituents were to occur. Formulations may contain more than 1 botanical ingredient; each may contribute to the final concentration of a single component. Manufacturers were cautioned to avoid reaching levels of plant constituents that may cause sensitization or other adverse effects. Industry should continue to use good manufacturing practices to limit impurities in the ingredient before blending into cosmetic formulations. The Expert Panel concluded that these ingredients are safe in the present practices of use and concentration in cosmetics, when formulated to be nonsensitizing.</p>
Benzene, 1,2-dimethoxy- (Veratrole 1,2-dimethoxybenzene ortho-dimethyl hydroquinone)	Y		No Data
Benzeneacetic acid, phenylmethyl ester (Benzyl Phenylacetate)	Y		No Data
Bulnesia sarmienti, ext. (Bulnesia sarmientoi, verawood, Guaiaol)	Y		No Data
Caprylyl Alcohol	Y		Capryl alcohol or Caprylic alcohol???
Castoreum	Y		No Data
Celery seed (Apium graveolens L.)	Y		No Data
Chamomilla Recutita (Matricaria) Flower Oil	Y		https://www.cir-safety.org/sites/default/files/chamom032016tent.pdf
Citrus Aurantium Bergamia (Bergamot) Fruit Oil	Y		
Citrus Aurantium Dulcis (Orange) Peel Oil	Y		

Ingredient List – Johnson's Baby Powder & Shower-to-Shower

Chemical	Baby Powder	Shower-to-Shower	
Citrus Medica Limonum (Lemon) Peel Oil	Y		
Citrus Nobilis (Mandarin Orange) Peel Oil	Y		
Copper Chlorophyll	Y		<p>https://cosmeticsinfo.org/ingredient/chlorophyllin-copper-complex-0</p> <p>The Food and Drug Administration (FDA) has approved Chlorophyllin-Copper Complex as a color additive exempt from certification. As a color, Chlorophyllin-Copper Complex may be safely used for coloring dentifrices when it conforms to FDA specifications. FDA has also permits the use of Chlorophyllin-Copper Complex in Over-the-Counter (OTC) internal deodorant drug products. Internal deodorant drug products are taken internally to reduce odors from conditions such as colostomies, ileostomies or fecal incontinence.</p> <p>More safety Information: All color additives used in foods, drugs and cosmetics in the United States must be approved by FDA and listed in the Code of Federal Regulations. In some cases, FDA requires that each batch of color produced for use in regulated products can be used only if it is certified by the agency to meet strict specifications. FDA maintains a laboratory especially for this purpose and color manufacturers must pay a fee to support this activity. FDA only approves colors after extensive review of all safety data and publication of the basis for its approval in the Federal Register.</p> <p>Link to FDA Code of Federal Regulations for Chlorophyllin Copper Complex</p> <p>https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=357.810&SearchTerm=chlorophyllin-copper https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=73.2125&SearchTerm=chlorophyllin-copper</p> <p>Chlorophyllin-Copper Complex is listed as CI 75810 in the Cosmetics Directive of the European Union and may be used as a coloring agent in all cosmetics and personal care products (see Annex IV). When used in cosmetic products in the European Union, this ingredient must be called CI 75810.</p> <p>Link to the EU Cosmetic Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:co0013</p> <p>You can learn more about the regulation and labeling of colors at: https://www.personalcarecouncil.org/colors-cosmetics-regulation-and-nomenclature-united-states</p>
Evernia Prunastri (Oakmoss) Extract (<i>evernia prunastri lichen extract</i>)	Y		No Data
Hex-3-en-1-yl acetate (3-Hexenyl acetate, (3E)-)	Y		<p>http://www.thegoodscentscompany.com/data/rw1130931.html#toafety</p> <p>European information : Most important hazard(s): S 24/25 - Avoid contact with skin and eyes.</p>
Methyl 2-(methylamino)benzoate (Methyl N,N-dimethylantranilate)	Y		No data
Methyl Hydrogenated Rosinate	Y	Y	No data

Ingredient List – Johnson’s Baby Powder & Shower-to-Shower			
Chemical	Baby Powder	Shower-to-Shower	
Musk Ketone		Y	https://echa.europa.eu/documents/10162/e6a84904-118b-447a-8766-f7bda48f7ce0 https://pubchem.ncbi.nlm.nih.gov/compound/6669#section=Safety-and-Hazards Signal: Warning GHS Hazard Statements <i>H351 (99.74%): Suspected of causing cancer [Warning Carcinogenicity]</i>
Nonyl Acetate	Y		https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/pr469.pdf https://pubchem.ncbi.nlm.nih.gov/compound/8918#section=Safety-and-Hazards http://www.thegoodscentscompany.com/data/rw1015611.html#tosafy European information : Most important hazard(s): <i>S 24/25 - Avoid contact with skin and eyes.</i>
Oils, styrax	Y		No data
Orris concrete (Iris pallida) (orris rhizome concrete butter (iris pallida))	Y		http://www.thegoodscentscompany.com/search3.php?qName=orris+rhizome+concrete+butter+%28iris+pallida%29&submit.x=0&submit.y=0 European information : Most important hazard(s): <i>S 24/25 - Avoid contact with skin and eyes.</i>
Indisan (Sandela) reaction product (Sandela)		Y	Sandela
Tanacetum vulgare, ext.	Y		No data
Thymus Vulgaris (Thyme) Oil	Y		
Tromethamine		Y	https://online.personalcarecouncil.org/ctfa-static/online/lists/cir-pdfs/PR630.pdf
Undecan-2-one	Y		http://www.thegoodscentscompany.com/data/rw1021151.html#tosafy European information : Most important hazard(s): <i>S 24/25 - Avoid contact with skin and eyes.</i>
1,5-Dimethyl-1-vinylhex-4-en-1-yl benzoate	Y		https://pubchem.ncbi.nlm.nih.gov/compound/Linalyl_benzoate#section=Cellular-Locations http://www.thegoodscentscompany.com/data/rw1030541.html

APPENDIX E

Photographs of Body Powder Products and Their Warnings





LOT#19008W

**Angel
Of mine™**

ANGEL OF MINETM Baby Powder is especially formulated to soothe and give a fresh, clean and fragrant feeling to your baby's delicate skin. Made of the finest talc, it helps to absorb excess moisture, keeping the baby's skin dry and soft for ultimate comfort.

Directions: After changing diapers and after every bath, dry baby's skin thoroughly and apply liberally as needed.

Ingredients: Talc and Fragrance.

Warnings: • Keep out of reach of children.
• For external use only. • Avoid contact with eyes, discontinue use if irritation persists.
• Avoid ingestion or accidental inhalation by baby.
This product contains talcum powder and is intended for external use only. Frequent application of talcum powder in the female genital area may increase the risk of ovarian cancer. Seek professional assistance if needed. This product is sold by weight, not volume. Settling will occur during handling & shipping.



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